



Decision Matrix

Policy Options for 2018 General Assembly Session

TABLE OF CONTENTS

Staff Reports

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 Letter of Request (Delegates Garrett, Landes, O'Bannon III and Stolle)	1
Mandated Staffing Ratios in Assisted Living Facilities SJR 266 (Senator Dance)	6
Options for Increasing the Use of Telemental Health Services in the Commonwealth (Interim Report) HB1500 Item 30 #1c	11
Medical Use and Health Effect of Cannabis HJR 578 (Delegate Marshall) & House of Courts of Justice Letter Request	14
Life-Sustaining Treatment Guidelines Workgroup HB 2153 (Delegate Stolle)	27
Sustainability of the Prescription Monitoring Program SJR 285 (Senator Carrico, Sr.)	31
Heroin Use in Virginia HJR 597 (Delegate Marshall)	38
Should Medigap Policies Be Provided for Medicare Recipients under 65 Years of Age in Virginia? Letter of Request (Senator Wagner)	45

Membership	54
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PURPOSE OF DOCUMENT

- A. To review and discuss findings, public comments, and policy options regarding staff reports and other issues that came before the Commission and its Subcommittees in 2017.
- B. To develop legislative recommendations for the 2018 General Assembly Session.

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

Paula Margolis
Senior Health Policy Analyst

Study Mandate

In 2017, the Joint Commission on Health Care (JCHC) received a letter of request asking the Commission to study the creation of a registry of cases of abuse and neglect by a service provider of an individual receiving services through one of the three waivers serving children and adults enrolled in Medicaid who have developmental and/or intellectual disabilities (DD and ID). The three waivers are the Building Independence, Family and Individual Supports, and Community Living waivers.

Background

Types of abuse, neglect, and exploitation include: physical abuse, sexual abuse, mental and emotional abuse, improper use of another's funds or resources (applies to adults only), neglect and self-neglect. Legally mandated reporters include health service providers, guardians, home care workers, law enforcement officers, teachers, athletic coaches and others. 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:

- The Department of Social Services (DSS) administers Child Protective Services (CPS)
- The Department of Aging and Rehabilitative Services (DARS) administers Adult Protective Services (APS), although reporting and investigation is performed by local DSS offices
- The Department of Behavioral Health and Developmental Services Office of Human Rights (DBDS OHR) administers the Comprehensive Human Rights Information System (CHRIS) which includes reports of incidents involving individuals who receive DD and ID services
- The Department of Health Professions (DHP) investigates reports of 13 licensed provider types

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 the preponderance of the evidence did not support the allegation.

Individuals accused of alleged abuse, neglect and exploitation of children have the right to be notified in writing, to meet with the CPS worker assigned to the case, to hire an attorney and to appeal the disposition. Unfounded cases are only accessible to local DSS staff and are purged after one year, except under certain circumstances.

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% were substantiated or founded. 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); and, 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.

The *Code of Virginia* Title 15.2 Chapter 17 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 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.

Policy Options and Public Comments

Three comments were received:

- James Rothrock, Commissioner, Virginia Department of Aging and Rehabilitation Services (DARS)
- Jennifer Faison, Executive Director, Virginia Association of Community Services Boards, Inc. (VACSB)
- Jennifer G. Fidura, Executive Director, Virginia Network of Private Providers (VNPP)

POLICY OPTIONS	Support	Oppose
Option 1. Take no action		
Option 2. By letter of the JCHC Chair, request that the Secretary of Health and Human Resources identify an appropriate agency to convene a work group to determine the needs, policies, statutory and regulatory language, costs (including staffing and ongoing operations), to identify the appropriate agency to develop and manage a registry of complaints of abuse, neglect and exploitation against individuals providing direct care services to individuals enrolled in the three waivers.		DARS Virginia Network of Private Providers, Inc.
Option 3. Introduce language amending the <i>Code of Virginia</i> §8.01-46.1 (Disclosure of employment-related information; presumptions; causes of action) and <i>Code of Virginia</i> §40.1-27 (Preventing employment by others of former employee) to strengthen protections from legal challenges for previous employers providing work history, performance and other reference information to potential new employers.	VACSB, Inc. Virginia Network of Private Providers, Inc.	
Option 4. Introduce legislation to mandate that candidates seeking employment providing direct care to waiver enrollees submit letters from past employers describing certain aspects of their employment—for example, their work histories, pay rates, or reasons for their termination (and perhaps letters from instructors or others for individuals who are applying for a first job).		VACSB, Inc. Virginia Network of Private Providers, Inc.
Option 5. 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.	Virginia Network of Private Providers, Inc.	
Option 6. Introduce legislative language to provide immunity from civil liability to licensed waiver providers related to disclosure of job performance of candidates seeking employment as direct care providers to waiver enrollees, similar to the language in §15.2-1709 of the <i>Code of Virginia</i> .	VACSB, Inc. Virginia Network of Private Providers, Inc.	

Public Comment Excerpts

James Rothrock, Commissioner, Virginia Department of Aging and Rehabilitation Services

“We have significant concerns about the fiscal impact of such a registry and felt the presentation should address this more. This fiscal impact is of particular concern given the Administration is winding down...A complaint listing may leave the state vulnerable and may not achieve intended results. Allegations of adult abuse are quite complex.”

Jennifer Faison, Executive Director, Virginia Association of Community Services Boards, Inc.

“...The VACSB believes that a creation of a registry would be challenging for two reasons:

1. There would be considerable time, money and effort involved in its creation and maintenance without a thorough understanding of whether it has the ability to impact negative outcomes, and
2. Both code and regulations would require significant revision. For example, currently, for the adult population, there is no state entity that makes a formal determination that abuse or neglect has occurred; determinations are made by the employer and may or may not be included in the employee’s personnel record. An agency would have to be identified, given the authority and funded in order to take on the creation and maintenance of a registry.

Policy Option 3 – Support

Policy Option 6 – Support

Policy Option 4 – Oppose, Comment: CSBs already have a limited pool of qualified individuals from which to hire. If an individual was out of the workforce for a number of years for any reason, that individual may not have the ability to produce a recent letter of reference. Also, a previous employer may have gone out of business, leaving the employee with no point of contact for a letter of reference. Finally, this would represent an unfunded mandate on employers who would need to absorb the administrative costs of having to provide this type of detailed letter for every employee who leaves.”

Jennifer G. Fidura, Executive Director, Virginia Network of Private Providers

“The Virginia Network of Private Providers (VNPP, Inc) can support Options #3 or #6 both of which would provide protections to employers who give more comprehensive references on former employees. As current licensing regulations only require “Results of reasonable efforts to secure job-related references and reasonable verification of employment history” [12VAC35-105-430], that language could also be made more specific when the regulations are next revised.

The creation of a “registry” would be challenging for two reasons:

There would be considerable time, money and effort involved in the creation and maintenance, and both code and regulations would require significant revision. Currently, for the adult population, there is no state entity that determines that “abuse or neglect” has occurred; determinations are made by the employer and may or may not be included in the employee’s personnel record.

Adult Protective Services is concerned for the welfare of the individual; they may, or may not, open an investigation if the threat of harm has been eliminated, eg., the individual has been moved, the suspect employee has been removed, etc. And when they do find that an individual is in need of protective services, it is the provider’s responsibility to ensure that those services are in place – APS may or may not focus on an individual employee.

Additionally, DBHDS does not “independently” investigate every allegation; regulations require action on the part of the provider and DBHDS monitors the provider’s compliance. Therefore, there is no finding by DBHDS.

The finding that an individual either abused or neglected an individual in their care would, therefore, be solely the determination of the employer and certainly subject some significant variation. It should be noted that terminations of employment for “abuse” are, on occasion, not found by VEC to constitute “gross misconduct” which is the benchmark for denying unemployment. VEC would, in those cases, award unemployment payments.

While we appreciate, and applaud, the intent of the request, the first step should be greater protections for employers to provide immunity from civil liability (Option #3 or #6), the “tightening” of the DBHDS regulations as described above and the addition of a requirement to both maintain information on past employees in sufficient detail and have a policy/procedure in place that articulates the amount and type of information which should be given in a reference to another human services employer.

In summary, VNPP, Inc. can support Options #3 or #6; we also can support Option #5, but feel that it is better handled through the regulatory process. We strongly oppose Option #4 as something that would be unmanageable and would potentially be a barrier to employment for an individual through no fault of their own.”

Mandated Staffing Ratios in Assisted Living Facilities

Paula Margolis
Senior Health Policy Analyst

Study Mandate

Senate Joint Resolution 266 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.

Background

Assisted living facilities (ALF) are congregate home-like settings housing four or more adults who are aged, infirm or disabled. They provide 24/7 supervision and oversight of the physical and mental well-being of an individual, housekeeping, meals, medication management, transportation, and other services. ALFs are varied in type and may be for-profit or not-for-profit; affiliated with a faith-based organization; small, stand-alone operations or part of a large national chain. ALFs may serve mixed populations (needing different levels of care) in the same unit or they may have 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).

Neither Medicare nor Medicaid pays 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, which is a state- and locally-funded grant program that pays for room and board for individuals who meet income and other eligibility criteria. In Virginia, Medicaid does pay a per diem rate of \$49.50 for persons living in ALFs who are enrolled in the Alzheimer's Assisted Living Waiver to help pay for direct care services, although the waiver is due to expire the end of 2017 with no current plans for renewal.

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 stage IV dermal ulcers, pose an imminent physical threat to self or others, need continuous licensed nursing care, or have physical/mental health needs that cannot be met, as determined by the facility.

Current 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 a provisional, six-month license for ALFs with significant issues which need to be addressed immediately. Each resident must have an individualized service plan that is based on their needs which 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 staff required to meet the direct care needs of their residents
- They must have written back up plans for when regular staffing plans cannot be met
- They must report safety incidents to DSS within a day of occurrence

- Virginia specifies the training required of individuals who provide direct care
- Virginia regulations require that each room have a call signal system for residents to use when they need immediate attention
- Residents may also wear remote signaling devices to use when needed when they are not in their rooms
- In ALFs without call buttons, 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 used 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 (e.g., many residents need assistance with bathing and prefer to bathe at the same time of day) and could lack the flexibility needed to provide adequate care.

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. DSS needs resources in order to create reports that can be easily produced on a regular basis to help identify problems and track trends over time.

ALF 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 (CNA) represented a third of all nursing staff, and 27% were resident caregivers or non-certified nursing assistants. The turnover rate among nursing staff was 24% 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 their direct care staff compensation equals \$14.54 (wages and benefits) per hour with total staffing costs of \$465,745 per year - adding 3 more staff would raise costs by \$2,490 per resident per year.

ALF Costs and Reimbursement

Genworth Financial¹ estimated that in 2019, the median cost of assisted living in Virginia will be approximately \$4,300 per month. The current AG monthly rate (approximately \$1,220) covers about 28% of the projected 2019 monthly cost. Resident SSI income (except for a small monthly 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. ALF administrators report that they must carefully

¹ <https://www.genworth.com/about-us/industry-expertise/cost-of-care.html>

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.

Recent Developments

A 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 will be compared to those determined by use of the current form. It is expected that the new tool will be available in 2017 but its use will be voluntary; ALFs may still choose the method they use 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 before making 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 (including, Georgia, Idaho, Indiana, Maine, Mississippi, Missouri, Michigan, New Mexico, North Carolina, and South Carolina). Some of these states 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 suggested 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. A 'one size fits all' approach may not serve the wide variety of community structures.

Policy Options and Public Comments

The JCHC received four comments:

- Judy Hackler, Executive Director, Virginia Assisted Living Association
- Keith Hare, Virginia Health Care Association – Virginia Center for Assisted Living
- Dana Parsons, Vice President & Legislative Counsel, LeadingAge Virginia
- Ms. Claire E. Jacobsen, member of the Arlington County Commission of Aging/Long-Term Care Residences Committee

POLICY OPTIONS	Support	Oppose/Concerns
Option 1. Take no action		
Option 2. By letter of the JCHC chair, request that the Department of Social Services determine explicit minimum staffing ratio requirements for day, evening and overnight shifts	Ms. Claire E. Jacobsen	Virginia Assisted Living Association Virginia Health Care Association LeadingAge Virginia
Option 3. Introduce a budget amendment to raise Auxiliary Grant rates (amount to be determined)	Virginia Assisted Living Association Virginia Health Care Association LeadingAge Virginia	
Option 4. By letter of the JCHC Chair, request that the Secretary of Health and Human Resources direct the Department of Social Services to field a Request for Information (RFI) for enhancing data reporting capabilities	Virginia Assisted Living Association Virginia Health Care Association LeadingAge Virginia	

Public Comment Excerpts

Judy Hackler, Executive Director, Virginia Assisted Living Association

“The Virginia Assisted Living Association (VALA) highly recommends the JCHC support the policy options 3 and 4 that were recommended in the report to introduce a budget amendment to raise the Auxiliary Grant (AG) rate and to request the Secretary of Health and Human Resources to direct the Department of Social Services (VDSS) to field a Request for Information (RFI) for enhancing data reporting capabilities. VALA has been informed by several assisted living (AL) providers they would be able to admit and to retain residents who qualify for the AG rate if the AG rate were increased. Many AL communities do not accept new admissions of residents who qualify for the AG rate due to it being significantly underfunded, which then forces many of those residents to acquire housing at nursing home facilities at a significantly higher rate to the government...Increase of the AG rate helps to stabilize accurate placement of residents into long term care communities based on their acuity needs instead of on their financial resources.

VALA does not support option 2 of requesting VDSS to determine explicit minimum staffing ratio requirements for day, evening and overnight shifts. VDSS is currently in the process of completing the Comprehensive Revision of the Standards for Licensed Assisted Living Facilities that is expected to have an effective date of February 1, 2018. This comprehensive revision is the result of many years of thoroughly reviewing the current requirements and taking into considerations current resident populations, service practices, available and pending technology, and comments from many stakeholders including VALA, the Alzheimer’s Association, local Ombudsmen, family members, several Virginia agencies, and several other industry specific associations.”

Keith Hare, Virginia Health Care Association – Virginia Center for Assisted Living

“...Option 2: We believe that this option is duplicative and unnecessary in light of the pending overhaul of assisted living regulations that have a target effective date of February 1, 2018...We think these regulations and their more stringent approach to staffing should be allowed to move forward and take effect before consideration of additional requirements is considered.

Option 3: We strongly support additional funding for Auxiliary Grants (AG)...the current rate is not sufficient to allow for facilities to serve many AG recipients if any at all. A higher rate that is closer to the cost of care for these individuals would serve as a strong incentive to get them the best care possible.

Option 4: We support providing additional resources to DSS to better track and provide data to policymakers and providers across the Commonwealth. Better data will lead to better health care outcomes and help guide all assisted living providers across the Commonwealth to embrace best practices and approaches to the provision of resident-centered care.”

Dana Parsons, Vice President & Legislative Counsel, LeadingAge Virginia

“New comprehensive assisted living regulations will become effective on February 1, 2018, and they provide for increased levels of staffing within special care units and overall enhanced resident care. Generally, we feel that the best approach is to allow these regulations to be implemented to determine their effectiveness before moving forward with the development of staffing standards...We strongly support the introduction of a budget amendment to increase the auxiliary grant rate because the current rate is too low and does not provide adequate funding to care for many of the complex medical needs of residents...We strongly support the ability for DSS to have enhanced reporting capabilities.”

Claire E. Jacobsen, member of the Arlington County Commission of Aging/Long-Term Care Residences Committee

We “recommend Option 2: By letter of JCHC Chair request that the Department of Social Services (DSS) determine explicit minimum staffing ratio requirements for day, evening and overnight shifts. We must ensure safe staff to resident ratios.”

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

Paula Margolis
Senior Health Policy Analyst

Study Mandate

HB1500 Item 30 #1c - The Joint Commission on Health Care (JCHC) shall 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 Commonwealth in the 21st Century...The Joint Commission on Health Care shall submit an interim report to the Joint Subcommittee Studying Mental Health Services in the Commonwealth in the 21st Century by November 1, 2017 and a final report of its findings to the Joint Subcommittee by November 1, 2018.

Background

The Joint Subcommittee Studying Mental Health Services in the Commonwealth 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 to expanding telemental health services, including: provider, workforce, financial, client/patient, policy, and preventive care barriers. 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; expanding the number of specialists available to individuals living in health professional shortage areas; and streamlining psychiatric contracting by the Community Services Boards (CSB). The activities include the following:

Project Echo

Project Echo uses tele-technology and the *spoke and hub* model (where experts are at a hub and clinical providers are the spokes) to provide clinical support and education to health care providers, such as primary care doctors, who are not working in behavioral health settings but serve individuals with substance use and mental health conditions. In 2016, a pilot Project Echo program was initiated in Virginia with one-year funding from the Substance Abuse and Mental Health Services Administration (SAMHA). The project will launch in the Fall of 2017 and include three hub partners (University of Virginia, Virginia Commonwealth University School of Medicine and Virginia Tech-Carilion) that will provide subject matter experts for on-line didactic training and clinical guidance on addiction disorders with plans for expanding topic areas over time. Hubs will also oversee the rotation of specialists, curriculum development, physical site hosting and contribute evaluation scientists who will work with the University of New Mexico (creators of Project Echo) to evaluate the program. Funding of \$300,000 per year is needed to continue and expand the program beyond the first year, and to pay for office space and administrative costs, provide payment to hub providers, purchase technology and equipment, and pay for connectivity fees.

Updating the resources for the Southside Training and Telehealth Academy (STAR)

STAR is a training program that is part of the Virginia Health Workforce Development Authority located in Martinsville, Virginia and provides training and certification for health care providers seeking to use advanced telemedicine and telehealth systems for rural and medically-underserved populations. STAR offers Board Certified Telemental Health Provider training for mental health professionals, Certified Telemedicine Clinical Presenter Training, the Certified Telehealth Coordinator/Technical Professional program, and Health Insurance and Portability Accounting Act (HIPAA) training on protecting personally identifiable health information. The STAR platform, website and content were created in 2012 and need to be expanded and updated; the Telemental Health work group estimates that \$100,000 would be needed to accomplish these goals.

Support a pilot to expand access to behavioral health in Southwestern Virginia involving the Virginia Telehealth and Appalachian Telemental Health Networks

The work group recommended that the Commonwealth leverage funding to implement a pilot telemental health network using Appalachian Regional Commission (ARC) and Tobacco Region Revitalization Commission (TRRC) grants, which have overlapping footprints. There are 25 Virginia counties that qualify for ARC funds, of which 16 also qualify for TRRC funds (Bland, Buchanan, Carroll, Dickenson, Floyd, Grayson, Henry, Lee, Patrick, Russell, Scott, Smyth, Tazewell, Washington, Wise and Wythe). Tasks would include:

- Developing a readiness assessment tool to determine current resources, network capability, knowledge and telehealth technology needs for providers as they join the network,
- Providers will have access to compiled provider information, resources and advice on using telehealth within their practice, recommended equipment, and continuing education opportunities

Develop a directory of telehealth providers that can be accessed by individuals and used by non-behavioral health providers to refer patients in Appalachia and possibly statewide

The work group estimated that \$50,000 annually would be required to implement and maintain a 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 directory would be limited to providers licensed and living in Virginia. 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 and ongoing outreach efforts to enroll providers.

Request that the JCHC conduct a study to determine the feasibility of central or regional telepsychiatry resources that could serve all the CSBs in the state

CSBs vary widely in their catchment areas, type of location (rural, urban, suburban), demand for psychiatric services, and availability of professional providers. Currently each CSB is responsible for contracting with psychiatrists, regardless of the method used to deliver services (in-person, telemental health). While some CSBs may have a need for multiple full-time psychiatric staff, others may only require psychiatric coverage for a few hours per week. The work group recommended that the DBHDS act as a central contracting agent for all CSBs, in order to increase efficiency and service coverage, and that the Joint Commission on Health Care perform a study of the feasibility of centralizing and standardizing contracts.

Policy Options

The JCHC received no comments on this study.

Please note: The Joint Subcommittee to Study Mental Health Services in the 21st Century has not yet formally considered or voted on the recommendations in the report from the Telemental Health Work Group on Policy Development. The Work Group’s full set of findings and recommendations for action were issued in October of 2016, and are the subject of ongoing study by the JCHC, as directed by the General Assembly. Five recommendations (represented by options 2-6 below) have been identified by the Work Group as being the most amenable to implementation now, and the Work Group is recommending to the Subcommittee that funding (for options 2-5 below) be provided for such implementation in the 2018 General Assembly session. Since Joint Subcommittee members will be considering these recommendations in a meeting later this fall, JCHC members may choose to not vote on them at this time.

Policy Options
Option 1: Take no action
Option 2: The JCHC supports the Joint Subcommittee to Study Mental Health Services in the 21 st Century if it chooses to introduce Budget language in the 2018 session to appropriate \$300,000 per year to operate Project Echo.
Option 3: The JCHC supports the Joint Subcommittee to Study Mental Health Services in the 21 st Century if it chooses to support the use of Virginia Tobacco Region Revitalization Commission and Appalachian Regional Commission funds to create an Appalachian Telemental Health Network Pilot
Option 4: The JCHC supports the Joint Subcommittee to Study Mental Health Services in the 21 st Century if it chooses to introduce Budget language in the 2018 session to appropriate \$50,000 to create a state-wide on-line network directory of telemental health providers.
Option 5: The JCHC supports the Joint Subcommittee to Study Mental Health Services in the 21 st Century if it chooses to introduce Budget language in the 2018 session to appropriate \$100,000 to update and expand the Southwest Training Academy and Resource Center telehealth website, platform and content.
Option 6: The JCHC supports the Joint Subcommittee to Study Mental Health Services in the 21 st Century if it chooses to request that the JCHC conduct a study on consolidating psychiatric telemental health contracting through the DBHDS.

Medical Use and Health Effects of Cannabis

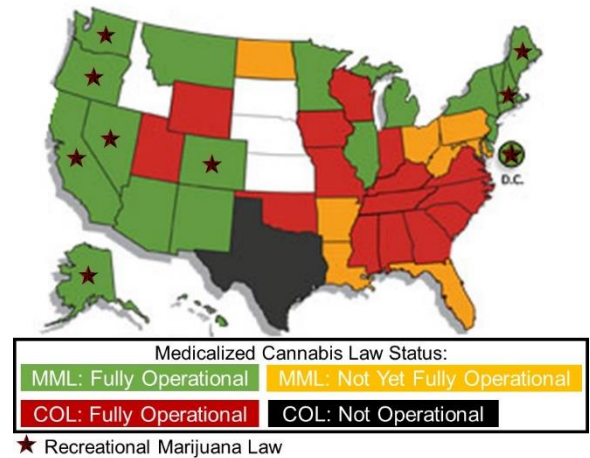
Andrew Mitchell
Senior Health Policy Analyst

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 and agreed to by the Joint Commission on Health Care members at the May 23, 2017 work plan meeting.

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.



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. However, THC-A readily decarboxylates (changes) into THC – the primary psychoactive (intoxicating) substance in cannabis. As a result, maximum potential percentage THC for any cannabis product is defined as the sum of the total percentage THC and approximately 90% THC-A. Since Virginia Code permits a maximum of 5% THC in either oil:

- Psychoactive effects of CBD oil will be limited to psychoactive effects from 5% 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% THC if THC-A decarboxylates into THC at the processing and/or consumption stages.

Regulatory steps that could be considered to avoid decarboxylation of THC-A into THC include:

- Cold storage of THC-A by processors to ensure stability and stability testing overseen by the Department of Health Professions (DHP).
- Prohibition on heating of THC-A oil by patients who can otherwise legally invoke an affirmative defense in the use of these oils.

Therapeutic Effects of Cannabis for Medical Use

The strength of the evidence base on therapeutic effects of THC and CBD is highly limited, and even more so for THC-A. Among the 11 conditions under consideration by the House Courts of Justice, only

one – patient-reported MS symptoms – has strong evidence of therapeutic effects. Conversely, there is limited evidence of effectiveness in treating clinician-measured MS symptoms and appetite or weight loss associated with HIV/AIDS; insufficient evidence to support or refute the existence of an association of effectiveness for ALS, cachexia, cancers and epilepsy; and limited evidence that cannabis is ineffective in treating glaucoma and dementia.

Detrimental Effects of THC and CBD

The majority of evidence on adverse effects of cannabinoids relates to therapeutic products containing THC alone or THC combined with CBD. On the one hand, there is evidence that CBD is well-tolerated. On the other, CBD and/or THC have been associated with both serious and non-serious Adverse Events (AEs). Additionally, although cannabis does not appear to be contra-indicated for other drugs, 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:

- 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. 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. Among the 31 MML States:

- Four permit physicians to make recommendations for conditions that are not explicitly listed in Code.
- Around 70% delegate authority to agencies overseeing medical marijuana programs to consider the addition of new conditions to those approved in Code through a petition-based approval process. One COL State also has adopted such a process.

Health Effects of Cannabis Use

Adverse Associations of Cannabis Use

In recent reviews of adverse associations between cannabis use and a variety of health outcomes, the evidence base is more often than not too limited or insufficient to draw conclusions. Themes that are emerging in research on cannabis and health include:

- Certain populations may be at highest risk for adverse health outcomes, such as adolescents and individuals with genetic pre-disposition to psychotic disorders.
- 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.
- 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.

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 (<i>no association</i>)		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

† 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

Cannabis Legalization and Decriminalization

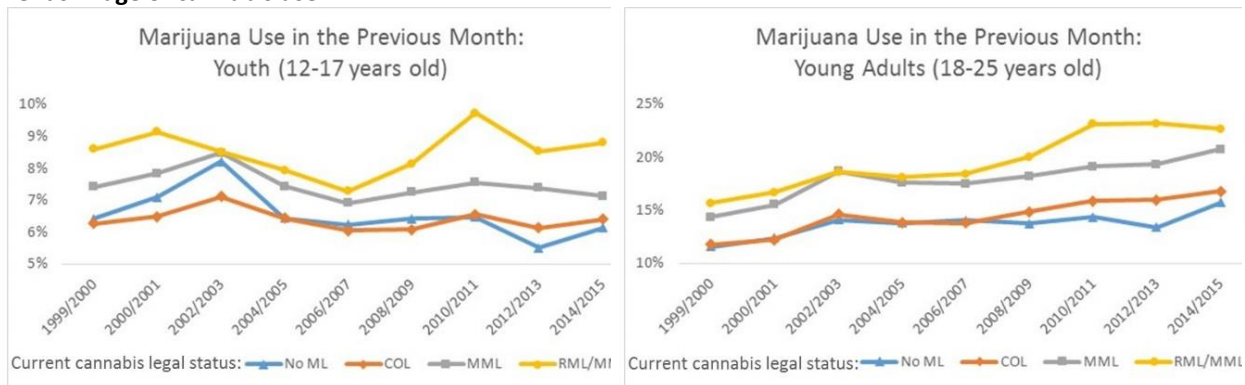
Recurring themes that emerge in research on the status of States’ cannabis laws and cannabis use, age of cannabis initiation and impaired driving include:

- 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



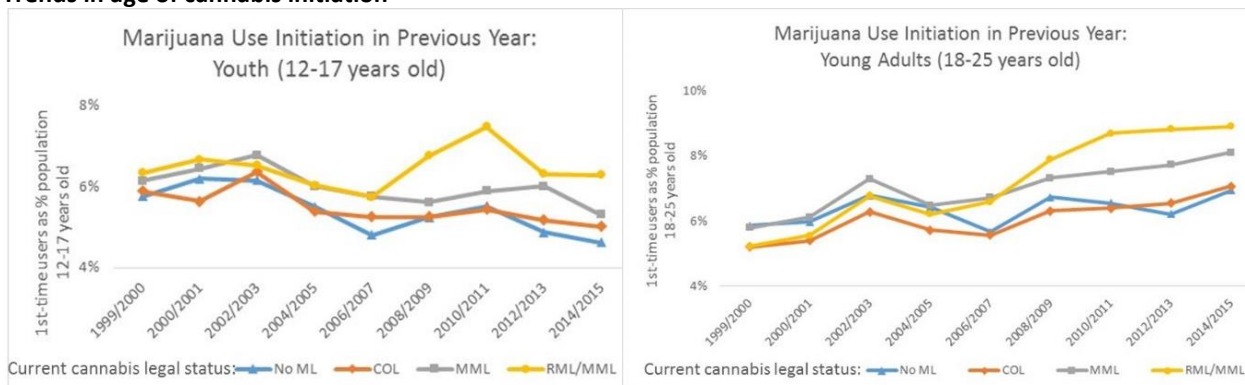
In terms of associations between passage of MMLs and RMLs and changes in cannabis use:

- 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.

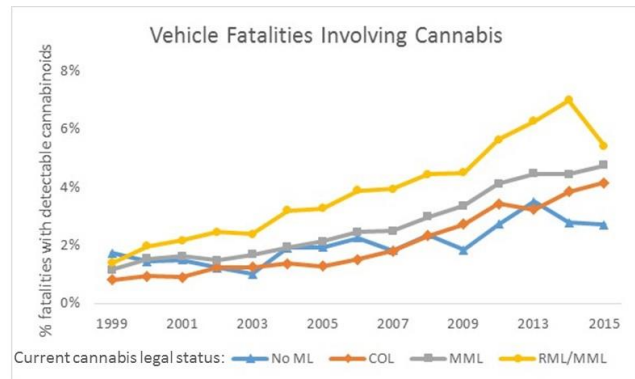
Trends in age of cannabis initiation



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. As with many other areas of study, the limited research hampers ability to draw firm conclusions.

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). 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. In the RML context, there is evidence of increased collisions in RML States compared to non-RML States, but no changes in crash fatality rates.



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.

Policy Options and Public Comment

756 comments were received – from 744 individuals and 12 organizations – of which 732 supported option 9, 17 supported option 1, and varying numbers supported or opposed other options. Comments submitted on behalf of organizations included:

- Mary Crozier, Chair; Nancy Hans, Past Chair; Regina Clarke, Vice Chair; Jen Cooper, Treasurer; and Elaine Brown, Secretary: **Community Coalitions of Virginia (CCoVA) Board**
- Regina Clark, Coalition Coordinator: **Focus on Response and Education to Stay Healthy (FRESH) Prevention Coalition**
- Keri Jones, Coordinator: **Greater Augusta Prevention Partners (GAPP)**
- Ashley Kenneth, on behalf of: the **National Multiple Sclerosis (MS) Society**
- Rebecca S. Hubble, Coordinator: **Pulaski Community Partners Coalition (PCPC)**
- Abigail Meier, Facilitator: **Radford Youth Adult Partnership (RYAP)**
- Regina Whitsett, Executive Director: **Substance Abuse Free Environment, Inc. (SAFE)**
- Michelle Wagaman and Kathy Reed, Council Co-Chairs: **Virginia Association of Community Services Boards (VACSB) Prevention Services Council**; Kim Faison, Executive Director: **VACSB**
- Katy Sawyer, Executive Director: **Virginia Breast Cancer Foundation (VBCF)**

- Deborah Hommer, President, and Yvette Negron-Torres, Vice President: **Virginians for Medical Freedom (VMF)**
- Christa Shifflett, Executive Director: **Warren Coalition**
- Mary Crozier, Chair; Mike Reiss, Vice Chair; and Lynn Hightower, Secretary: **Youth and Community Action Team (YCAT)**

Policy Option	Stakeholder position:	
	In Support	In Opposition
Option 1: Take No Action	<ul style="list-style-type: none"> ▪ Tracy Ballard ▪ Community Coalitions of Virginia (CCoVA) ▪ Focus on Response and Education to Stay Healthy (FRESH) ▪ Brittoni Gordon ▪ Greater Augusta Prevention Partners (GAPP) ▪ Jennifer Lewis-Cooper ▪ Octavia Marsh ▪ Doug Perry ▪ Pulaski Community Partners Coalition (PCPC) ▪ Suzanne Phelps ▪ Radford Youth Adult Partnership (RYAP) ▪ Ava Saureace ▪ Dennis Southers ▪ Substance Abuse Free Environment, Inc. (SAFE) ▪ Virginia Association of Community Services Boards (VACSB) Prevention Services Council ▪ Warren Coalition ▪ Youth and Community Action Team (YCAT) 	
<i>Policy options to address decarboxylation of THC-A into THC in THC-A oil:</i>		
Option 2: Introduce legislation to amend §54.1-3408.3(A) of the Code of Virginia, redefining THC-A oil as a processed Cannabis plant extract that contains not more than 5% <u>maximum potential</u> THC by weight	<ul style="list-style-type: none"> ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (support if action taken, and if <u>maximum potential</u> THC by weight is reduced to 1.5%) ▪ Monica Morris ▪ Virginia Breast Cancer Foundation (VBCF) 	<ul style="list-style-type: none"> ▪ Beth Collins; Lisa Smith (“does not support”)

Policy Option	Stakeholder position:	
	In Support	In Opposition
<i>OR one or both of the following:</i>		
Option 3: Introduce legislation to amend §18.2-250.1(C) of the Code of Virginia, making smoking or heating of THC-A oil above naturally occurring temperatures a disqualification for an affirmative defense for possession of THC-A oil	<ul style="list-style-type: none"> ▪ Tracy Ballard ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (support if action taken) ▪ Brittoni Gordon ▪ Doug Perry ▪ Suzanne Phelps ▪ Ava Saureace ▪ Dennis Southers ▪ VBCF 	<ul style="list-style-type: none"> ▪ Beth Collins; Lisa Smith (believes “is unnecessary”)
Option 4: By letter of the JCHC Chair, request that DHP amend 18 VAC 110-60 by: requiring THC-A oil processors to ensure that the percentage of THC remains within 10% of the level measured for labeling under 18 VAC 110-60-290, and; establishing a stability testing schedule for THC-A oil processors	<ul style="list-style-type: none"> ▪ Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, Warren Coalition (support if action taken, but oppose the percentage specified [10%]) 	<ul style="list-style-type: none"> ▪ CCoVA, FRESH, GAPP, VACSB Prevention Services Council, YCAT (oppose if action taken)
<i>Policy option related to THC-A and CBD oil dispensing requirements:</i>		
Option 5: Introduce legislation to amend the Code of Virginia: <ul style="list-style-type: none"> • Requiring THC-A and CBD oil processors to register their formulations with DHP for a fee – with each registration application including a list of all active and inactive ingredients and any other items deemed necessary by DHP – for the purposes of including THC-A and CBD oils in the list of substances tracked by the Prescription Monitoring Program (PMP) • Requiring pharmacists who dispense THC-A and/or CBD oil to enter dispensing information (e.g., dose, quantity) into the PMP at the time of dispensing 	<ul style="list-style-type: none"> ▪ Tracy Ballard ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (support if action taken) ▪ Brittoni Gordon ▪ Monica Morris ▪ Doug Perry ▪ Suzanne Phelps ▪ Ava Saureace ▪ Dennis Southers ▪ VBCF 	<ul style="list-style-type: none"> ▪ Beth Collins (does not support unless it can be done “low-cost”) ▪ Lisa Smith

Policy Option	Stakeholder position:	
	In Support	In Opposition
<i>Policy option related to monitoring of Adverse Events:</i>		
Option 6: By letter of the JCHC Chair, request that DHP and VDH review models in other States for the monitoring and reporting of Adverse Events related to use of cannabis for medical purposes, providing a report to the JCHC with a recommended model for Virginia by October 1, 2018	<ul style="list-style-type: none"> ▪ Tracy Ballard ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (support if action taken) ▪ Beth Collins ▪ Brittoni Gordon ▪ Monica Morris ▪ Doug Perry ▪ Suzanne Phelps ▪ Ava Saureace ▪ Lisa Smith ▪ Dennis Southers 	
<i>Policy options related to the process for adding new qualifying conditions as an affirmative defense for use of THC-A or CBD oils:</i>		
Option 7: Introduce legislation to amend the Code of Virginia authorizing DHP to add new conditions, through administrative rulemaking, for which practitioners may provide written certifications for THC-A and CBD oils, requiring DHP to: <ul style="list-style-type: none"> • Constitute a regulatory advisory panel, composed of at least a majority of Board-certified physicians, whose purpose will be to evaluate petitions for the addition of new conditions and make recommendations for their approval or denial to the Director of DHP; • Establish processes that ensure opportunity for public comment related to regulatory advisory panel evaluations; • For new conditions approved by the Director of DHP: draft regulations to add the condition through the Administrative Procedures Act Process 		<ul style="list-style-type: none"> ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (oppose if action taken)

Policy Option	Stakeholder position:	
	In Support	In Opposition
<ul style="list-style-type: none"> • With <i>or</i> without sending determinations to the Chairs and ranking minority members of the HWI and Senate and Education and Health Committees by January 1 of each year before adding the condition for GA opportunity to legislatively provide otherwise 		
OR		
<p>Option 8: By letter of the JCHC Chairman, request DHP to form a stakeholder work group to review models in other States of delegated approval to executive agencies to approve new conditions, providing a report to the JCHC with a recommended model for Virginia by October 1, 2018</p>		<ul style="list-style-type: none"> ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (oppose if action taken)
OR:		
<p>Option 9: Introduce legislation to amend §54.1-3408.3(B) of the Code of Virginia to allow physician recommendation for any condition determined by the physician to benefit from THC-A or CBD oil</p>	<ul style="list-style-type: none"> ▪ 732 individuals ▪ National MS Society ▪ VBCF ▪ Virginians for Medical Freedom (VMF) 	<ul style="list-style-type: none"> ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (oppose if action taken)

Policy Option	Stakeholder Position:	
	In Support	In Opposition
<i>Policy option related to non-medical use of cannabis:</i>		
Option 10: Introduce legislation to amend the Code of Virginia to authorize the Virginia Department of Taxation to administer, on THC-A and CBD oils, a consumer retail sales tax of 5.6% or a processor excise tax at 5.6%, with tax revenues deposited into a fund for the purposes of funding programs to prevent illicit cannabis use	<ul style="list-style-type: none"> ▪ Jim Whipkey 	<ul style="list-style-type: none"> ▪ CCoVA, FRESH, GAPP, Jennifer Lewis-Cooper, Octavia Marsh, PCPC, RYAP, SAFE, VACSB Prevention Services Council, Warren Coalition, YCAT (oppose if action taken) ▪ Beth Collins; Lisa Smith (“does not support”)

Public Comment Excerpts

672 of the public comments from individuals supporting option 9 were based on the following form letter:

“I write to you today in support of policy options #1 and #9 -- as outlined in the October 17, 2017 JCHC report Medical Use and Health Effects of Cannabis. Further, I oppose any recommendations that would reduce the percentage of THC available in qualified extracts below five percent -- the threshold that was unanimously approved by the legislature.

I am concerned that many of the proposed options in this document appear to be duplicative and contrary to existing law.

HB 1799/SB 1403, which was passed and signed into law in March, already addresses many of the concerns raised in this report. Specifically, the law:

- Authorizes a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy (the Board) and under the supervision of a licensed pharmacist, to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy.
- Requires that a practitioner who issues a written certification for cannabidiol oil or THC-A oil, the patient issued such certification, and, if the patient is a minor or incapacitated, the patient's parent or legal guardian register with the Board.
- Requires that a pharmaceutical processor shall not provide cannabidiol oil or THC-A oil to a patient or a patient's parent or legal guardian without first verifying that the patient, the patient's parent or legal guardian if the patient is a minor or incapacitated, and the practitioner who issued the written certification have registered with the Board.
- Provides an affirmative defense for agents and employees of pharmaceutical processors in a prosecution for the manufacture, possession, or distribution of marijuana.

Ninety-two percent of Virginians favor the legalization and regulation of doctor-recommended medical cannabis. The most effective thing that lawmakers could do would be to allow this regulatory system to be fully enacted, and to remove barriers that needlessly prevent doctors from making healthcare decisions that are in the best interest of their patients.

Please ensure that this process is implemented quickly and in the spirit of the law so that seriously ill Virginians may access these life-saving oils.”

26 of the public comments from individuals supporting option 9 were based on the following form letter:

“I am a constituent of Virginia, a concerned voter, and a member of Virginians for Medical Freedom (VMF). The principals of VMF have sent to JCHC via email a letter concerning the use of CBD and THCA oil. The principals wrote the letter on behalf of all VMF members, and have ask that you please vote Option 9, which would LET DOCTORS (not legislators) decide what conditions would benefit from CBD and THCA oil. I want to confirm that as a member of VMF I agree with voting for option 9, which is the less restrictive option.”

Among the 731 comments from individuals supporting option 9, several described personal medical situations that they felt could be better managed through the use of THC-A or CBD oils. Examples include:

Roger S. Sillmon, Troutville: “I am 63 years old with a long history of congenital and degenerative spine and leg problems. Although I was able to work for ~ 48 years, sometimes with terrible pain, I am now retired. The only significant pain relief available to me was oxycodone. Now that I do not have to undergo work place random drug tests (oxycodone was OK since I had a "prescription"), I am able to use marijuana for pain relief with NO negative side effects. I HAVE BEEN ABLE TO REDUCE THEN COMPLETELY STOP TAKING OXYCODONE WITH THE SUBSTITUTION OF MARIJUANA AND ONE SNRI DRUG.

It is ironic that oxycodone in my system was OK at my workplace although marijuana in my system would jeopardize my job!”

Sara Lissabet, Fairfax: “In 2014 I was injured on an improperly maintained utility cover and now suffer chronic pain as a result. This past summer my husband and I took an RV trip across country, during which I purchased a pain balm in Oregon. Before running out of the product, this product helped alleviate much of my chronic foot pain, my husband's sciatica, one sister's knee pain, another sister's gout and pain from a fractured sacrum, a nephew's tendonitis, and a friend's heel spur pain (all Virginia residents). It is tragic that we cannot obtain similar products in Virginia, so we all suffer daily pain as a result. (One sister became addicted to Vicodin but fortunately received treatment that allowed her to come off this opioid medication.)

It is difficult to comprehend that I become a "criminal" when I cross the Potomac River if I drive to DC to find something similar to bring home.

The scientific evidence continues to mount about the medical benefits of both CBD and THC. Please craft legislation to allow the doctors to decide how to medically treat their patients. Please help us to live more pain free lives.”

Michael Klemen, Doswell: “I am the parent of a child with severe Crohn's disease. She has been sick for 2/3 of her life. She has had 2 major surgeries removing her large intestine, parts of her small intestine, her rectum and tried every medicine available for Crohn's and NONE help her. We are currently scheduled to go to Mayo Clinic next week to see if they can help because doctors in Richmond, including MCV and doctor's at UVA have not been able to help her at all. She is 34, she has a Doctorate in Physical Therapy, she eats more healthy than nearly anyone but none of it does any good for her. Will medical Marijuana work for her? I do not know but we definitely need to try it. It has had great results in several studies. We have lived in VA for over 30 years, our family is here, our jobs are here, but if medical marijuana is not legalized soon in VA we may have to move somewhere else to try to help our child. We just built a new home we want to spend our retirement years in. Please help make it so we do not have to leave.”

Five of the public comments from organizations supporting option #1 were based on the following form letter (from: CCoVA, FRESH, GAPP, VACSB Prevention Services Council, YCAT):

“[Organization] supports Option 1: Take No Action (no further marijuana legislation should be passed in Virginia)

IF Action is Taken: [Organization] supports Option 2, with the exception that the cannabis plant extract contain not be more than 1.5% maximum potential THC by weight. If 5% is allowed, Virginia would be one of the top two states in the country with that high amount. The average THC allowed in limited access states is less than 1.5%. We support a 1.5% maximum potential THC by weight because the potency triples when heated.

[Organization] supports Option 3, 5 & 6

[Organization] OPPOSES Option 4, 7-10: We are concerned about the public health and safety of our citizens, especially our youth and young adults. Data show that cannabis legislation results in increased youth and adult usage, increased traffic fatalities, negative workplace impacts, adverse effects on mental health and mental health services, loss to family income, multiple drug use, adverse health effects, and lowered academic achievement. [Organization] supports FDA approved medicines only.”

Four of the public comments from organizations supporting option #1 were based on the same form letter as above with a difference regarding Option 4 (from PCPC, RYAP, SAFE, Warren Coalition):

“[Organization] SUPPORTS Option 4, as we think it is important products be consistently labeled when processed and sold. However, [Organization] OPPOSES the proposed 10% limit as this would allow the products to have too high of a potency level.”

Life-Sustaining Treatment Guidelines Work Group

Andrew Mitchell
Senior Health Policy Analyst

Work Group Mandate

In 2016, the JCHC voted for Policy Option #3 of the study “Development of Life-Sustaining Treatment Guidelines” to include in the 2017 JCHC work plan formation of a work group to do the following and report back to the JCHC in 2017:

- Study issues surrounding the provision of life-sustaining treatment decisions in Virginia
- Continue and extend discussions initiated by a work group formed as part of the “Development of Life-Sustaining Treatment Guidelines” study
- Focus on options for preventing or improving outcomes of life-sustaining treatment decision conflict

Background

§ 54.1-2990 of the Code of Virginia addresses circumstances in which a physician refuses to provide life-sustaining treatment that s/he determines to be medically or ethically inappropriate, but the determination is in conflict with a treatment preference expressed by a patient or proxy (e.g., Advance Directive, instructions by patient’s designated decision-maker). While the Code describes certain procedures to be followed by the physician who refuses to provide health care s/he determines to be inappropriate and provides a 14-day timeframe for resolution, the Code is silent on permissible treatment decisions if 14 days have passed but consensus has not been reached.

Workstreams

The Work Group identified three areas of focus related to disputes between patients/patients’ agents and providers on appropriateness of life-sustaining treatment: literature/data on contextual factors surrounding disputes; data on the frequency and characteristics of disputes in Virginia; and continued revisions to § 54.1-2990 to increase statutory clarity on resolution of disputes.

Contextual factors affecting disputes in life-sustaining treatment

There is significant potential for disagreements over appropriate life-sustaining treatment between family members and health providers: over one-third of deaths in the US take place in hospitals, with most of those deaths (over 80%) occurring after decisions are made to withhold or withdraw life-sustaining treatment. While conflicts between clinicians and families in general arise frequently in the ICU setting – and those related specifically to life-sustaining treatment account for the majority of ethics consultations in hospitals – it is estimated that the vast majority are resolved consensually.

Certain factors appear to either drive or protect against disputes over life-sustaining treatment. Driving factors include fundamentally different perspectives of patients and providers – such as different goals of care or perceived likelihood of success of treatment – but also process-related issues – such as lack of psychological support for families and perceived disregard for family or patient preferences. Conversely, other process-related factors – such as greater opportunity for discussions between providers and families – can protect against disputes.

The effect that these situations may have on providers in terms of moral distress is well-documented. In the UVA health system, for instance, 40% of ethics consultations over the past decade related to end-of-

life situations or treatment decision conflicts. While situations of treatment decision conflict are likely to exact a toll on patient family members as well, the literature exploring their perspectives is much more limited.

Virginia data on life-sustaining treatment disputes

To better understand the frequency of disagreements over appropriate life-sustaining treatment between family members and health providers, data were collected from 16 of 19 Virginia health systems, representing 90% of general acute care hospitals in the Commonwealth. The majority of health systems responding (9 out of 16) have in place a written, formalized process for handling situations of decision-making conflict between providers and patients’ families. In the last year, 50 cases went through the process set up to handle these situations, with around 30% resolved because of consensus and around 26% in which the patient died. Around 5% of situations remained intractable, and the patient was able to be transferred in around 2%. Of the seven health systems without a formal process, all but one expressed a desire to develop such a process, with most of those health systems not having done so to date due to lack of legislative clarity in how to address situations of intractable disputes over life-sustaining treatment.

Revisions to § 54.1-2990

Several guiding principles informed revisions to § 54.1-2990 undertaken by the workgroup. These included:

- Building off of revisions drafted in 2016 as part of the “Development of Life-Sustaining Treatment Guidelines” study
- Continuing to obtain input from all stakeholders, addressing concerns, and including safeguards for both patient and provider perspectives that do not exist in the current Statute language
- Ensuring that § 54.1-2990 outlines a complete process governing decisions to withdraw or withhold life-sustaining treatment, and provide clarity about an endpoint to this process
- Reflecting principles of due process

The following tables summarize revisions made by the workgroup, with the full set of revisions included in the Appendix of the presentation:

Workgroup revisions – additional safeguards to current Statute provisions

Current Statute provisions	Additional safeguard(s) proposed
<ul style="list-style-type: none"> • Physician is not required to provide medically/ethically inappropriate treatment 	<ul style="list-style-type: none"> • <u>Physician determination of appropriateness bounded by:</u> <ul style="list-style-type: none"> • Explicitly requiring patient’s medical condition as basis of determination • Preventing determination to be based on disability and other patient attributes that are not directly related to patient’s medical condition
<ul style="list-style-type: none"> • Physician shall make a reasonable effort to inform patient of reasons for the decision not to provide 	<ul style="list-style-type: none"> • <u>Add two levels of requirements of hospitals/physicians surrounding physician’s decision:</u> <ul style="list-style-type: none"> • Four process steps to formally review physician’s decision (e.g., 2nd medical opinion; interdisciplinary medical committee review)

Current Statute provisions	Additional safeguard(s) proposed
<p>medically/ethically inappropriate treatment</p>	<ul style="list-style-type: none"> Five points of written information required to be provided to patient/patient’s agent: (e.g., right of the patient to: an independent medical opinion; participate in medical review committee process; seek available remedies under the law)
<ul style="list-style-type: none"> Physician shall make a reasonable effort to transfer the patient and provide patient’s agent 14 days to transfer 	<ul style="list-style-type: none"> Retains requirements to facilitate transfer and provide 14 days for transfer
<ul style="list-style-type: none"> During 14-day window, life-sustaining treatment must continue 	<ul style="list-style-type: none"> Retains requirement to continue life-sustaining treatment and <u>requires hospital to facilitate access</u> to patient’s medical records by patients/patients’ agents

Workgroup revisions – safeguards for new proposed Statute provisions

New Statute provisions	Safeguard(s) proposed
<ul style="list-style-type: none"> Allows withdrawal/withholding of life-sustaining treatment after 14 days if no transfer possible 	<ul style="list-style-type: none"> For artificial food and nutrition: <ul style="list-style-type: none"> <u>Prohibits withdrawal/withholding</u> if its removal would be the sole mechanism to hasten death <u>Allows withdrawal/withholding</u> if its provision would hasten death, be harmful or medically ineffective, or be contrary to the patient’s wishes
<ul style="list-style-type: none"> Creates liability protections for physicians who abide by process requirements 	<ul style="list-style-type: none"> Following process requirements creates presumption of standard of care (civil liability) and protects from criminal liability absent gross negligence

Policy Options and Public Comment

Comments were received from the following 2 organizations:

- Maureen Hollowell: **Virginia Association of Centers for Independent Living (VACIL)**
- Brent Rawlings, Vice President & General Counsel: **Virginia Hospital & Healthcare Association (VHHA)**

Policy Option	Stakeholder position:	
	Support	Oppose
Option 1: Take No Action	<ul style="list-style-type: none"> ▪ Virginia Association of Centers for Independent Living (VACIL) 	
Option 2: Based on revisions to § 54.1-2990 proposed by the Work Group, introduce legislation to amend § 54.1-2990 of the Code of Virginia	<ul style="list-style-type: none"> ▪ Virginia Hospital & Healthcare Association (VHHA) 	

Public Comment Excerpts

In support of option 1, **VACIL** wrote that:

“The Commonwealth should not allow physicians or hospitals to end life sustaining treatment over the objections of the individual or the surrogate the individual elected to have represent them.

People with disabilities could have their treatment ended based on misperceptions about the impact of the individual’s disability, even if the individual had a directive to continue treatment.

Considering the seriousness of the end of treatment, the notice and procedures to permit the end of treatment over the objections of the individual or their surrogate must be transparent, easy to access, easy to understand and include adequate protections. The Code nor the recommendations provide for the transparency and protections needed.”

In support of option 2, **VHHA** wrote that:

“Legislative changes to Va. Code § 54.1-2990 are needed to address the unfortunate circumstances that arise in providing care at the end of life in a way that balances the need to ensure dignity and respect for patients and their families and protect vulnerable individuals, with respect and appreciation for the professional obligations of physicians and nurses. Hospitals are well equipped to provide this balance bringing together a variety of resources in multidisciplinary teams that are specifically trained to assist patients and their families in making decisions to continue or discontinue life sustaining treatments.

Current law at § 54.1-2990 allows a physician to transfer a patient for whom care has been requested that the physician believes is medically or ethically inappropriate. This provides the opportunity for the patient to continue to receive the requested care from another provider, but in practice, such transfers are not always possible when there is no other physician willing to carry out and accept the obligation to provide the requested treatment...

Recommendation 2 are needed to specify in statute appropriate actions to be taken in these situations where the minimum 14-day time period to effect a patient transfer has expired and a transfer is unable to be effected, but at the same time ensure needed balance to protect patients. The legislative changes also reflect principles of procedural due process and provide some liability protections for health care providers that act in conformance with the law.”

Sustainability of the Prescription Monitoring Program

Andrew Mitchell
Senior Health Policy Analyst

Study Mandate

In 2017, Senator Carrico, Sr. requested via SJR 285 that the JCHC 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 and agreed to by the Joint Commission on Health Care 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
- 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). 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.

The PMP has limited ability to assess impact on prescribing and dispensing practices through routine program data. 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). 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. However, methodological challenges limit the ability to attribute changes in outcomes to use of PDMPs.

PMP funding

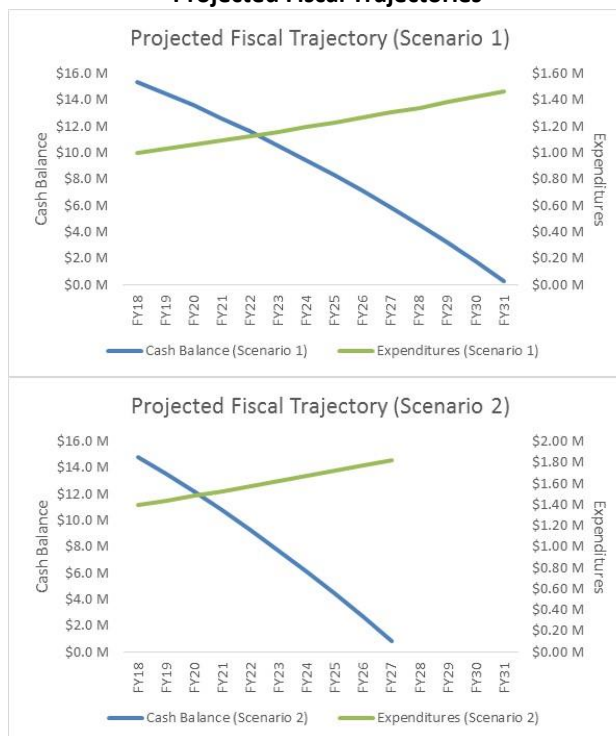
The PMP’s current budget is around \$875,000, which is expected to climb to at least \$1M by FY18. As indicated in the table below, the Purdue Frederick Company court settlement agreement funds support basic functionality, while there are currently additional sources of funds supporting time-limited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

Projected Fiscal Trajectories



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% 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.

Model 2: Controlled Substances Sales Tax

While Virginia does not currently tax prescription medicines (across the US, only one State taxes prescription medicines), it was estimated in 2011 that tax exemptions for controlled substances resulted in approximately \$32M in foregone revenue. Based on estimated sales of controlled substances in 2011, a retail sales tax of 0.013% to 0.026% 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, a flat point-of-sale controlled substances tax of \$0.08-\$0.14 would raise approximately \$1M to \$2M. 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 the 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% of health insurance policies in the State. A premium assessment would therefore apply only to policyholders in those markets. Based on premiums collected in 2016, an assessment of 0.01% - 0.02% 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 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% 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
- 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

Phase	Revenue source for PMP functionality		# years	Notes
	Basic	Enhanced		
Short-term	<ul style="list-style-type: none"> License fees AND/OR Tax on Controlled Substances AND/OR Health insurance premium assessment 	<ul style="list-style-type: none"> DHP at 100% 	<ul style="list-style-type: none"> 2-3 years 	<ul style="list-style-type: none"> Enhanced functionality supported by DHP using Purdue Frederick Company court settlement agreement funds Begins when Purdue Pharma LP \$3.1M integration grant funds spent (anticipated end FY18)
Medium-term		<ul style="list-style-type: none"> DHP at 50%; health systems / hospitals / provider practices at 50% 	<ul style="list-style-type: none"> 2-4 years 	<ul style="list-style-type: none"> 50% enhanced functionality supported by DHP using court settlement agreement funds Ends when court settlement agreement funds reach pre-determined floor (e.g., \$5M)
Long-term		<ul style="list-style-type: none"> Health systems / hospitals / provider practices at 100% 	<ul style="list-style-type: none"> Indefinite 	<ul style="list-style-type: none"> Remaining court settlement agreement funds allocated by DHP to respond to program needs

Policy Options and Public Comment

Comments were received from the following 2 organizations:

- Ralston King, Assistant Vice President of Government Affairs, **Medical Society of Virginia (MSV)**
- Richard Grossman, on behalf of the **Virginia Council for Nurse Practitioners (VCNP)**

Policy Option	Stakeholder position:	
	In Support	Opposed
Option 1: Take No Action	<ul style="list-style-type: none"> Medical Society of Virginia (MSV) Virginia Council for Nurse Practitioners (VCNP) 	
<i>Introduce legislation to amend the Code of Virginia authorizing the:</i>		
Option 2: Department of Health Professions (DHP) to <u>increase, by up to \$30, licensing fees of health professions</u> required to register with the Prescription Monitoring Program (PMP), provided that: <ul style="list-style-type: none"> • Annual fees/fee increases to support the PMP are deposited into a Virginia PMP fund, established by DHP and for the purpose of financing expenditures for basic PMP functionality 		

Policy Option	Stakeholder position:	
	In Support	Opposed
<ul style="list-style-type: none"> An enactment clause delays the effective date until the funds from the \$3.1M Purdue Pharma integration grant have been distributed 		
<p>Option 3: Department of Taxation to administer a <u>retail sales or point-of-sale tax of 0.02% OR \$0.10, respectively, on controlled substances</u>, provided that:</p> <ul style="list-style-type: none"> Tax revenues to support the PMP are deposited into a Virginia PMP fund, established by the Department and for the purpose of financing expenditures for basic PMP functionality An enactment clause delays the effective date until the funds from the \$3.1M Purdue Pharma integration grant have been distributed 		
<p>Option 4: Bureau of Insurance to <u>assess health insurers 0.015% of the total premium</u> of health plans in the individual, small employer and large employer markets, provided that:</p> <ul style="list-style-type: none"> Premium assessments to support the PMP are deposited into a Virginia PMP fund, established by DHP and for the purpose of financing expenditures for basic PMP functionality An enactment clause delays the effective date until the funds from the \$3.1M Purdue Pharma integration grant have been distributed 		
<p>Option 5: Introduce budget amendment authorizing DHP to use, after funds from the \$3.1M Purdue Pharma LP grant have been distributed, Purdue Frederick Company settlement agreement funds to support the integration of up to 100% of PMP users*</p>		
<p>Option 6: Authorize a Non-General Fund appropriations increase of \$110,000 for 1 Full-Time Equivalent position at the DHP to lead analyses drawing on PMP and other patient-level data sources that help the PMP meet its program goals of</p>		

Policy Option	Stakeholder position:	
	In Support	Opposed
promoting appropriate use of controlled substances for legitimate medical purposes, including deterrence of misuse, abuse and diversion of controlled substances		

*Regarding Option 5: If the proposed sustainability plan described above (see p. 35) is used, the intent is for DHP to use the court settlement agreement funds for integration until that fund reaches a predetermined floor (e.g. \$5M). Also, please note that this option was added after discussions with DLS indicated that this policy could be adopted in the upcoming session even if it didn't take effect until a future budget session.

Summary of Public Comments

Both MSV and VCNP feel that there is not a need to take action at this time given the amount of money remaining in the Purdue Frederick Company court settlement agreement funds. However, both recommend the formation of a stakeholder workgroup to identify the future needs and functionality of the PMP.

Heroin Use in Virginia

Stephen Weiss
Senior Health Policy Analyst

Study Mandate

In 2017, Delegate Marshall requested via House Joint Resolution 597 that the JCHC 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 study was included in the Joint Commission on Health Care 2017 work plan and approved by members.

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.

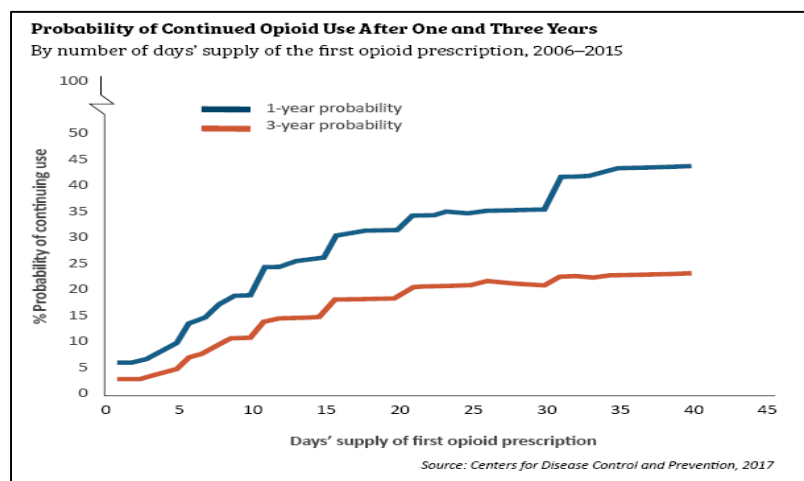
National Information

In the U.S., deaths from drug overdose involving heroin tripled from 8% in 2010 to 25% in 2015. The number of people indicating heroin use on the National Survey on Drug Use and Health (NSDUH) increased by 150% 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.

During the 1960s, 82% of heroin users seeking treatment reported using heroin as their first opioid; by 2010 the percent flipped, 75% of heroin users seeking treatment reported using prescription pain medicine first. 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%. In 2013, 59% of the heroin deaths involved one other drug; marijuana, cocaine and/or prescription opioid pain relievers.

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% of risk.

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; 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.

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% 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.

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

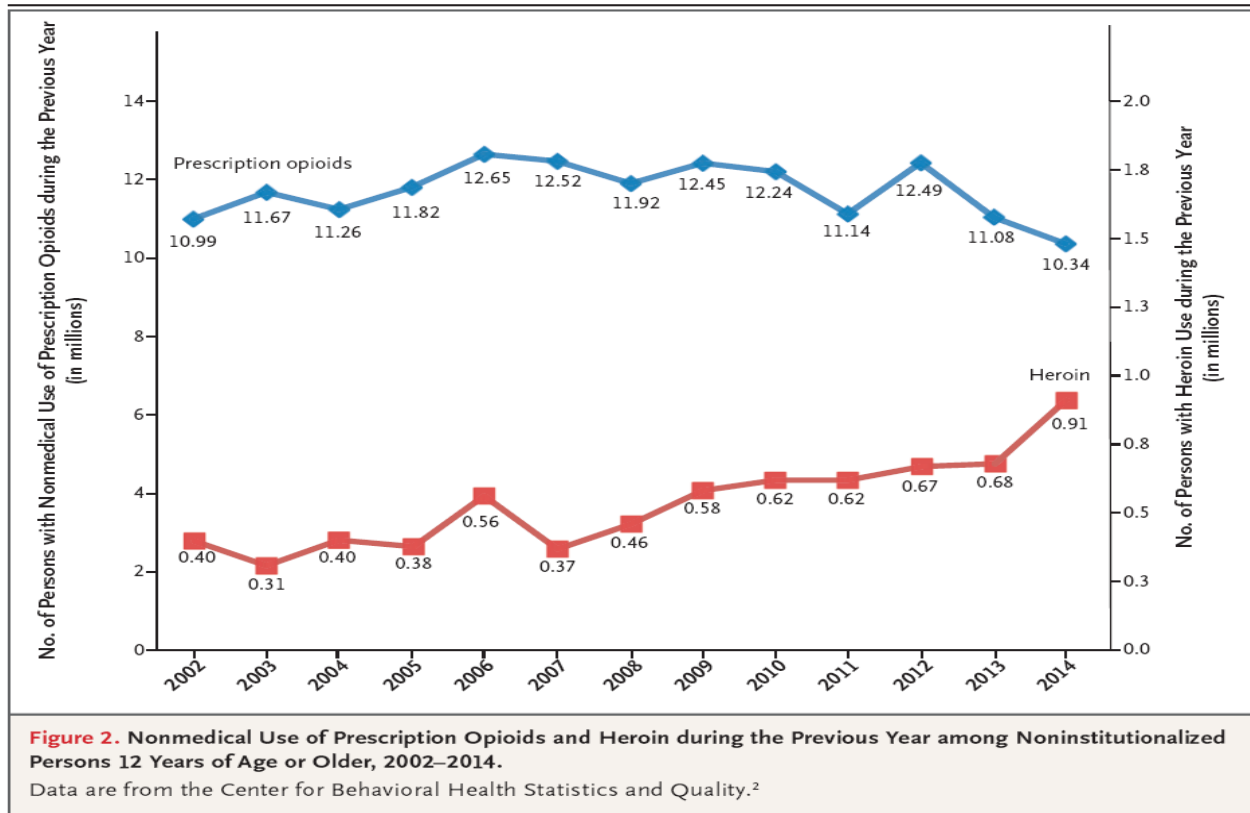
Drug Store	Evzio - Auto Injection		Narcan Spray	Generic Syringe		Generic Vial	
	0.4 MG (1 syringe)	2 MG/0.4 ML (1 syringe)	4 MG (2/pack)	1 MG/2 ML (2 syringes)	0.4 MG/ML (1 syringe)	0.4 MG/ML (10ML - 1 vial)	0.4 MG/ML (1 ML - 1 vial)
Rite Aid	\$1,863.25	\$2,171.55	\$140.50	\$39.47	\$19.90	\$112.44	\$19.54
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

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.

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.

RELATIONSHIP BETWEEN PRESCRIPTION-OPIOID AND HEROIN USE



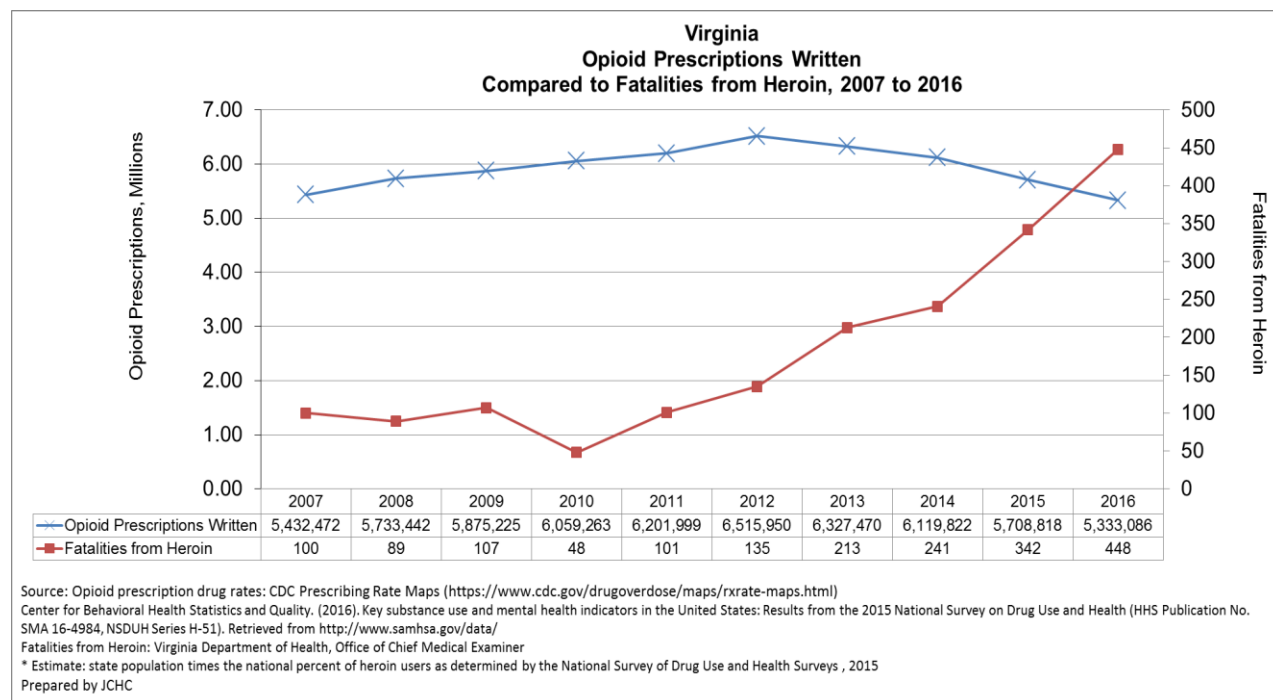
The Next Emerging Crisis: Synthetic Fentanyl

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.

Virginia Information

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% of the state population. The survey reports that heroin use went from 0.2% to 0.3% of the U.S. population from 2007 to 2015. 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% in 2016 when compared to 2015. OCME reports that in 2016, 57.4% of heroin deaths also included fentanyl.

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



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% increase over 2015. As of August 2017, naloxone was administered 3,186 times by EMS and may exceed 4,700 times by years end, a 47.7% 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/>

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 and 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/>

Policy Options and Public Comment

Five comments were received from the following individuals:

- Keri Jones, GAPP Coalition Coordinator, Greater Augusta Prevention Partners (GAPP)
- Jennifer Faison, Executive Director, Virginia Association of Community Services Boards, Inc.
- Regina Clark, FRESH Coalition Coordinator, Focus on Response and Education to Stay Healthy (FRESH)

- Regina Whitsett, Executive Director & Valerie Murphy, SAFE Opioid and Heroin Prevention Task Force Coordinator, Substance Abuse Free Environment, Inc. (SAFE)
- Carol Butz

The Policy Options for consideration are as follows:

Policy Options		Support	Oppose
Option 1	Take no action		GAPP SAFE FRESH Butz
Option 2	Introduce legislation to amend the Code of Virginia by adding in § 2.2-200 a section to make the Governor’s Executive Leadership Team on Opioids and Addiction permanent.	GAPP SAFE FRESH Butz	
Option 3	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. Require that all state and local agencies, including local law enforcement agencies, government and non-government hospitals, Community Services Board Boards, and any other entities receiving public funds from the Commonwealth, provide such data to the appropriate state agencies identified by the Governor’s Secretaries.	GAPP SAFE FRESH Butz	
Option 4	Request by letter of the JCHC Chair that the DBHDS or VDH (to be determined) study the feasibility of licensing “safe-injection” sites for users of heroin and other illegal drugs. Such study should include a review of sites already operating in other locations, legal barriers to licensing such sites and the costs and benefits associated with operating such sites. A report to the Commission detailing the results of the study will be provided by October 1, 2018.		GAPP SAFE FRESH Butz

Public Comment Excerpts

JCHC received five public comments on the study. Four of the commenters support options 2 and 3, and oppose options 1 and 4. One of the commenters requests an examination of membership and charge of the existing Governor's Substance Abuse Council rather than making the Governor's Executive Leadership Team on Opioids and Addiction permanent via Code.

Keri Jones, GAPP Coalition Coordinator, Greater Augusta Prevention Partners (GAPP)
Regina Clark, FRESH Coalition Coordinator, Focus on Response and Education to Stay Healthy (FRESH)
Regina Whitsett, Executive Director & Valerie Murphy, SAFE Opioid and Heroin Prevention Task Force Coordinator, Substance Abuse Free Environment, Inc. (SAFE)

All write in support of options 2 and 3 on behalf of their organizations. They oppose option 1 because taking no action will not positively impact the epidemic and they oppose option 4 because "safe injection" sites are not within the mission of prevention and education. Finally, they state that allowing the legal use of illicit drugs is not an appropriate solution.

Jennifer Faison, Executive Director, Virginia Association of Community Services Boards, Inc.

Regarding option 2, Ms. Faison writes that a more efficient option would be to re-examine the charge and membership of the existing Governor's Substance Abuse Council. Such a re-examination can avoid overlap of membership and insure that proper attention is focused on the current opioid crisis as well as to insure that the disease of addiction is at the "heart of the mission" regardless of the substance so that "strategies and creative problem solving" can be "translated across all substance use disorders."

Carol Butz

Ms. Butz writes in support of options 2 and 3. She opposes option 1 because "something has to be done." She also opposes option 4 because it will "open a whole can of worms for more abuse."

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

Stephen Weiss
Senior Health Policy Analyst

Study Mandate

By letter to the JCHC 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 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 ages 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 ages 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% of all Medicare beneficiaries spent 20% or more of their income on out-of-pocket expenses (including 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.²

² 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.

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% nationally and 78% 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, 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.

Medigap enrollment and premium data for those under age 65 provided by three states (CO,ME,TN) suggest that an

average of 4.61% 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

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

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 ages 65 and over.

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% 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 following table displays the different features of each state:

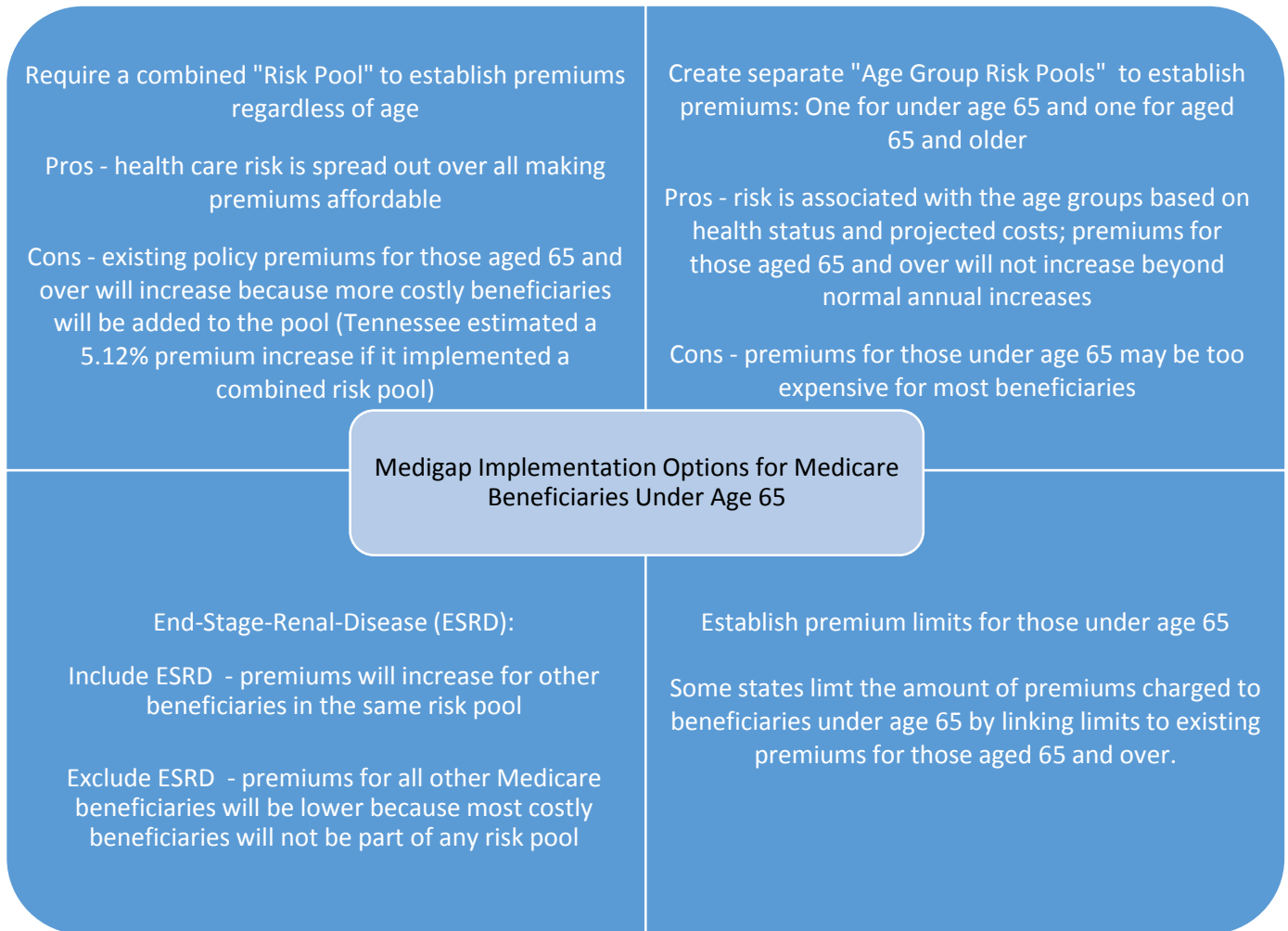
Description of Medigap Insurance Requirements for Medicare Beneficiaries Under Age 65					
State	Premium Rating	Required Coverage	Plan Types Required	Enrollment Period	Rating Provisions
Colorado	Attained Age Rating	Disabled including ESRD	All plans offered to over 65 population	6 months from first day 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>. American Health Insurance Plans (AHIP). Under age 65 disabled - Access to Medigap. May 2017.

Conclusions

Thirty-three states currently require health insurance companies selling Medigap to those aged 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, often sicker and more costly than those aged 65 and older.

As noted in the report, there are a variety of options a state may choose if it requires health insurance companies to sell Medigap insurance to people under the age of 65. The following chart illustrates some of the options:



Policy Options and Public Comment

Five comments were received from the following individuals:

- Kyle Shreve, Director of Policy; Virginia Association of Health Plans
- Jane Bretzin, MSW; Virginia Insurance Counseling and Assistance Program Medicare Counselor
- Jill A. Hanken, Health Attorney; Virginia Poverty Law Center
- Lisa Walker, Vice President, Advocacy Resources; Virginia Insurance Counseling and Assistance Program Counselor with Bay Aging
- Mike Wilkins, Leesburg, VA

The Policy Options for consideration are as follows:

Policy Options	Support	Oppose
Option 1: Take no action	Virginia Association of Health Plans	
Option 2: Introduce legislation to amend the Code of Virginia by adding in Chapter 36 of Title 38.2 a section requiring the Virginia Bureau of Insurance to adopt regulations requiring insurers selling Medicare Supplemental policies in the Commonwealth to make those policies available regardless of age or disability; requiring an open enrollment period under the same conditions as required by federal law and requiring premiums be established based on sound actuarial practice.		
Option 3: Introduce legislation to amend the Code of Virginia by adding in Chapter 36 of Title 38.2 a section requiring all insurers selling Medicare Supplemental policies in the Commonwealth to make those policies available regardless of age or disability <i>under the same conditions and requirements as policies sold to those at age 65, which allows insurers to use current practices to establish premiums (one risk pool)</i>	Mike Wilkins	

Policy Options	Support	Oppose
<p>Option 4: Introduce legislation to amend the Code of Virginia by adding in Chapter 36 of Title 38.2 a section requiring all insurers selling Medicare Supplemental policies in the Commonwealth to make those policies available regardless of age or disability with the following conditions:</p> <ul style="list-style-type: none"> Establishing an open enrollment period with the same conditions as required by federal law for those age 65 and over <i>Allowing insurers to charge different premiums for those under age 65 but limiting the cost of premiums to no more than 3 times the cost of premiums for those at age 65.</i> 	<p>Jill A. Hanken Health Attorney Virginia Poverty Law Center, prefers this option because it includes ESRD</p> <p>Lisa Walker VP, Advocacy Resources, Bay Aging</p> <p>Jane Bretzin, MSW VICAP Medicare Counselor</p>	
<p>Option 5: Introduce legislation to amend the Code of Virginia by adding in Chapter 36 of Title 38.2 a section requiring all insurers selling Medicare Supplemental policies in the Commonwealth to make those policies available regardless of age or disability, excluding end-stage-renal-disease and with the following conditions:</p> <ul style="list-style-type: none"> Establishing an open enrollment period with the same conditions as required by federal law for those age 65 and over <i>Allowing insurers to charge different premiums for those under age 65 but limiting the cost of premiums to no more than 2 times the cost of premiums for those at age 65.</i> 	<p>Jill A. Hanken Health Attorney Virginia Poverty Law Center, not the best option because it excludes ESRD</p> <p>Lisa Walker VP, Advocacy Resources, Bay Aging</p>	
<p>Option 6: Introduce legislation to amend the Code of Virginia by adding in Chapter 36 of Title 38.2 a section requiring all insurers selling Medicare Supplemental policies in the Commonwealth to make those policies available regardless of age or disability and with the following conditions:</p>		

Policy Options	Support	Oppose
<ul style="list-style-type: none"> Establishing an open enrollment period with the same conditions as required by federal law for those age 65 and over Requiring insurers to charge a premium for those under age 65 that is no greater than the premium the insurer charges for age 65 (see Maine, Community rating) 		
<p>Option 7: Introduce legislation to amend the Code of Virginia by adding in Chapter 36 of Title 38.2 a section requiring all insurers selling Medicare Supplemental policies in the Commonwealth to make those policies available regardless of age or disability and with the following conditions:</p> <ul style="list-style-type: none"> Establishing an open enrollment period with the same conditions as required by federal law for those age 65 and over and requiring the Bureau of Insurance to establish by regulation which plans should be made available, with periodic review; and To establish by regulation a method based on sound actuarial practice what the premiums should be provided. 		

Public Comment Excerpts

JCHC received five public comments on the Medigap study. Three of the commenters support option 4, two of the three support option 3. One of the commenters support option 3 and one supports option 1.

Kyle Shreve, Director of Policy, Virginia Association of Health Plans (VAHP)

Mr. Shreve, on behalf of the 9 commercial and Medicaid Managed Care Organizations the VAHP represents, writes in support of option 1, take no action. Mr. Shreve states that options 3 and 6 that include a single risk pool will cause all premiums to be high and will raise premiums on those aged 65 and over. He cites a Tennessee study that found that rates for those aged 65 and over “will increase by 5.12%” if Tennessee adopted a single risk pool for Medigap policies. Mr. Shreve states that options 2, 4, 5, and 7 will allow for separate risk pools based on sound actuarial practice. Under options 2 and 7 the premiums for Medigap policies will be very high and “not valuable for the individual.” Under options 4 and 5 the premiums for those under age 65 will be limited, putting the “long-term stability of the entire product at risk.” Mr. Shreve states that any policy decisions to make Medigap available to those under age 65 should include an “actuarially sound insurance pool.”

Jane Bretzin, MSW, VICAP Medicare Counselor

Ms. Bretzin writes in support of option 4. “In our VICAP program, we receive several calls each month from new Medicare beneficiaries under the age of 65 who are requesting information on Medigap insurance. Currently we must tell them that they are not eligible to purchase Medigap in our area.” Ms. Bretzin provides the following examples: “a wife called on behalf her husband who was told that he needed a heart transplant but that the hospital would not go forward with this procedure unless he had supplemental insurance, especially for the postsurgical expenses. When I had to inform her that there were no Medigap plans for [those] under 65, her response was akin to ‘so we just let him die?’” Ms. Bretzin points out that people with ESRD “are not eligible for Medicare Advantage Plans and, therefore, must be in Fee-for-Service Medicare.” While Ms. Bretzin states that she is “strongly in favor of offering Medigap plans to disabled under 65 she would not want this to result in across the board, above average, increases in the premiums for the 65 and up beneficiaries.”

Lisa Walker, Vice President, Advocacy Resources and VICAP Medicare Counselor at Bay Aging

Ms. Walker writes in support of either option 4 or 5. Ms. Walker states that she gets “calls nearly daily from folks who are on disability and new to Medicare looking for a Medigap (Medicare Supplement) plan.” Callers comment that “they are being discriminated against because they are disabled and it is not fair.” Ms. Walker provides some examples as follows, “a person suffering from cancer who is getting chemo therapy, which is covered under Part B, they are responsible for the 20% Medicare doesn’t cover. Many people with Rheumatoid arthritis get Remicade infusion treatments, which run around \$10,000 a treatment, so a person’s costs would be \$2,000. Clients who either divorce or lose their spouse and were covered by spouse’s plan are losing their coverage and left with nothing to replace it.” Ms. Walker further notes that Medigap can help keep “folks off of Medicaid”.

Jill A. Hanken, Health Attorney, Virginia Poverty Law Center

Ms. Hanken writes in support of options 4 or 5 but states that option 4 is the best because it does not exclude ESRD. Ms. Hanken supports a separate insurance product for those under age 65 and the inclusion of ESRD because the out-of-pocket costs are so high. She notes that only 3 states “where such coverage is offered” exclude ESRD.

Mike Wilkins

Mr. Wilkins writes in support of option 3. Mr. Wilkins states that “The other options, although well thought out, do not provide enough protection for the very people who might be able to afford a Medigap policy. For example, Option 5 excludes covering payments for those persons with ESRD, one of the chief causes for a person to become eligible for Medicare. Options 6 and 7 could put the premiums out of reach for those persons already in financial distress but who are trying to stay off of Medicaid. Mr. Wilkins states that while Option 3 can cause premiums to increase for other Medigap recipients but those increases should be negligible because the under-65 Medicare recipients will be in a large pool of Medigap subscribers. Mr. Wilkins cautions against allowing insurance companies to put individuals into separate risk pools because the policy costs will be too high for the beneficiaries.

In a separate email Mr. Wilkins writes that many individuals could afford to pay for Medigap insurance if they did not have to pay for the high out-of-pocket expenses and he noted that, “Allowing these recipients to continue to draw down their limited finances means that they will eventually qualify for Medicaid, which will increase the load on Medicaid budgets. Medigap insurance for those under 65 costs the state nothing, since the state contributes nothing toward Medigap insurance for those over the 135% FPL.” Mr. Wilkins provides several examples of the need for Medigap for those under age 65. He indicates that, “disabled persons in Virginia with regular fee Medicare who need an organ transplant cannot be added to an organ transplant list. The medical centers will not consider patients for organ

transplants unless the patient has the Medigap coverage to pay for the significant deductibles that accumulate during and after a transplant.” He also notes that “insurance companies in Virginia are not required to accept new subscribers with ESRD.” Being on regular fee Medicare with the high costs of dialysis means the person will eventually be on Medicaid.

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