Decision Matrix

Policy Options for 2020 General Assembly Session

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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 in 2019.
B. To develop legislative recommendations for the 2020 General Assembly Session.

Language Development Milestones and Parent Resources for Young Deaf/Hard of Hearing Children

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Study Mandate

Senate Bill 1741 (Senator Edwards, 2018) would have required the selection of language development milestones for Deaf or hard of hearing (D/HH) children 0-5 years old, creation of parent/educator resources, and annual language milestone assessments/results reporting for D/HH children 0-5 years old. The bill was Passed By Indefinitely in the Senate Education and Health Committee and sent to the Joint Commission on Health Care (JCHC) for consideration.

Background

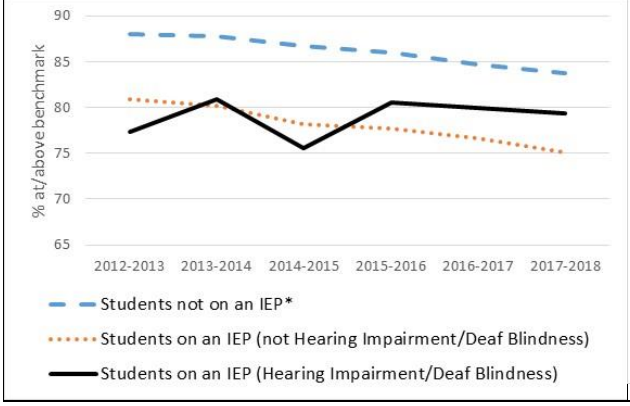
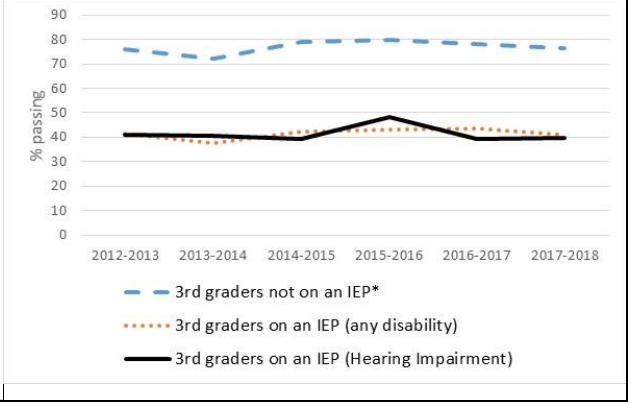
Childhood hearing loss is a low incidence condition that historically has adversely affected language acquisition and development. Approximately 100-200 children born each year in Virginia are diagnosed with hearing loss, with an estimated 95 percent born to hearing parents. Any degree of hearing loss raises risks of delays in language acquisition and literacy, and historically, most D/HH children arrive at kindergarten language-delayed. There is a consensus that acquisition of any language is foundational to literacy in any language and broader social-cognitive development, and that it must begin early in life for full potential to be realized. Main communication options for D/HH children include sign language (e.g., American Sign Language [ASL]), spoken (oral-aural) language with or without visual supplements, and written language. No consensus exists on which communication approaches are optimal for language development/literacy.

In Virginia, six State agencies support D/HH children through screening/diagnosis, developmental /education services and family support. The following are the three primary services and supports.

- The Early Hearing Detection and Intervention (EHDI) Program – overseen by the Virginia Department of Health (VDH) – provides families information on/referral to newborn hearing screening, follow-up testing and early intervention services.
- The "Infant & Toddler Connection of Virginia" – overseen by the Department of Behavioral Health and Developmental Services (DBHDS) –provides Early Intervention (EI) services to children 0-3 years old not developing as expected or with medical condition(s) that can delay normal development. EI services are determined through an Individual Family Service Plan (IFSP).
- Early Childhood Special Education (ECSE) services – overseen by the Virginia Department of Education (VDOE) – are specially designed instruction to meet unique needs of children with disabilities. ECSE services and supports are determined through an Individualized Education Program (IEP).

Language development among D/HH children 0-5 years old in Virginia is not directly measured. However, beginning in preschool, achievement in *literacy* is measured by VDOE through Phonological

Awareness Literacy Screening (PALS) and SOL tests. Although PALS does not include all D/HH children (e.g., those who cannot and/or do not make use of hearing technologies), around two-thirds of D/HH children on IEPs take the PALS beginning in kindergarten. Trends in PALS/SOL results are presented below.

Phonological Awareness Literacy Screening (PALS) kindergarten results	3rd grade Standards of Learning (SOL) English reading test results
	

* May include children ever diagnosed with hearing loss but not in need of IEP-based accommodations

Report recommendations on Senate Bill 1741

A stakeholder workgroup was convened to discuss issues raised in Senate Bill 1741. Although there were some points of consensus (e.g., early language acquisition is critical for full language and cognitive development, including literacy; parents of D/HH children should be able to choose preferred language(s) and mode(s) of communication), points of disagreement persisted relating to most aspects of the bill. Based on workgroup input and research conducted for the study, the following summarizes JCHC staff recommendations related to Senate Bill 1741 (please note that these recommendations do not reflect workgroup consensus).

Recommendation	**Rationale**
• Key terms should be defined, including language, communication modality, forms of English, Deaf	• Several terms used in SB 1741 are subject to varying interpretations and some terms have "industry" meanings
• Change agency assigned to lead the implementation of SB 1741 from DBHDS to the Virginia School for the Deaf and the Blind (VSDB)	• Whereas expertise of DBHDS is not specific to deafness and programming is limited to children 0-3 years old, VSDB's expertise is directly relevant to D/HH children and its mission is to provide education to D/HH persons 0-21 years old • Note: VSDB's estimated fiscal impact is ~$155K for Years 1 and 2, ~$23-$35K ongoing (DBHDS' estimated fiscal impact for SB 1741 was ~$200K for Years 1 and 2, ~$33K ongoing)
• Change requirements for constitution of Advisory Committee by stipulating that VSDB will: 1) determine *size* of	• Legislating exact committee size/composition risks omitting relevant perspectives

Recommendation	Rationale
Advisory Committee and 2) ensure *balanced membership*	• Similar legislation in other States has evolved to provide greater State agency authority over determining committee specifics
• Stipulate that the Parent Resource should be based on pre-existing resource guides	• VDH and VDOE currently support production by VCU of two parent-oriented resource guides which provide much of the information stipulated in SB 1741
• Change basis of milestones away from "standardized norms" to currently available assessments that are appropriate for evaluating progress toward age-appropriate language	• Requiring milestone selection based solely on standardized and/or norm-referenced instruments may unduly limit choice of appropriate milestones given that multiple non-standardized and/or non-norm-referenced instruments exist that may be appropriate for selecting milestones
• Require that milestone data include additional characteristics of assessed children	• Collecting data on characteristics of children assessed (e.g., by geographic region or communication approaches) could more directly inform agency programming • Note: VDOE's estimated fiscal impact for data collection is ~$95K for Year 1, ~$45K ongoing; DBHDS' estimated fiscal impact is unknown due to current procurement process for new EI data collection system

Alternative approaches to Senate Bill 1741

The study explored alternative approaches to addressing issues raised in SB 1741. The following summarizes JCHC staff recommendations for action the Commission members may wish to consider in place of or in addition to Senator Edward's bill.

Using existing literacy data to track language development outcomes

Current initiatives to integrate agency data may provide an opportunity to longitudinally track literacy outcomes of *all* children ever diagnosed with hearing loss before the age of three and who are part of the Virginia public schooling system. English literacy may be considered an outcome/proxy indicator for language acquisition since literacy cannot develop in the absence of language development. Additionally, written English is the sole form of communication shared by the great majority of D/HH children and is tracked by VDOE through PALS and SOL assessments. The Virginia Longitudinal Data System (VLDS) currently links data from 6 participating agencies – including VDOE – and VDH is currently in the process of onboarding EHDI data on children 0-3 years old diagnosed with hearing loss (anticipated in early 2019). When VDH EHDI data are onboarded to the VLDS, literacy outcomes tracked by VDOE at the kindergarten and early grade school levels (via PALS) and later grade school levels (using SOL testing) can be linked to all children ever diagnosed with hearing loss – including those who, through Cochlear Implants and/or hearing aids, participate in school without the use of an IEP – to measure progress in literacy.

Recommendation

Use the Virginia Longitudinal Data System (VLDS) as a basis for reporting on literacy outcomes of children diagnosed with hearing loss beginning at the kindergarten level, by linking literacy-related data from VDOE and hearing loss-related data from VDH's EHDI program.

Building on existing informational resources

The anticipated revision of existing "Green" Parent Resource Guide – provided to families of children 0-3 years of age diagnosed with hearing loss by VDH's EHDI program – can serve as a basis on which to integrate information on milestones. The revision process could include stakeholder input on language milestone selection and/or the provision of information on milestones developed in other States.

In addition to printed Resource Guides, information provided by State agencies relevant to D/HH children could be better aligned. Multiple workgroup participants highlighted difficulty in knowing where to turn for information when a hearing loss diagnosis first is received. Additionally, how each agency fits into the system of services and supports is complicated and not always entirely evident to the public. Improved public understanding of roles of state agencies involved with D/HH children and families could be beneficial.

Recommendation

Request that relevant State agencies a) incorporate language milestones into existing parent resource guides, and b) ensure that provision of information to families of D/HH children is consistently messaged, easily accessible and user-friendly.

Building on Existing Agency Initiatives Addressing Provider-side Barriers to Accessing Services

Geographic barriers to accessing EI services could be addressed through Medicaid reimbursement for EI services delivered by telepractice. DBHDS maintains a list of Teachers of the Deaf and Hard of Hearing (ToDHH) qualified to deliver EI services. According to DBHDS, although the total number of ToDHH statewide is adequate to serve the EI needs of the State's D/HH children, their geographic placement constitutes a barrier to accessing services outside of metropolitan areas. Although DBHDS is currently seeking DMAS approval to cover EI services delivered by telepractice, a recent DMAS memo that clarifies existing telehealth policy does not provide a process to include new/changed coverage (e.g., EI services).

Recommendation

Strengthen existing agency initiatives to identify opportunities for Medicaid reimbursement of telehealth-delivered EI services.

Exploring Opportunities for Early Exposure of Families to Deaf Role Models

Because childhood hearing loss is a low incidence condition, hearing parents often have had little previous contact with D/HH persons. The potential positive impact of involvement of D/HH persons in systems of services and supports is widely recognized, and several States support programs in which D/HH adults provide information and/or EI services to families. In particular, the "Deaf Mentor" program model emphasizes instruction in ASL and exposure to Deaf culture. Virginia currently does not support mentoring programs involving D/HH adults.

Recommendation

Identify opportunities to connect families of D/HH children with D/HH adults through mentoring programs to increase uptake of EI services and assistance to families in sign- and non-sign-based communication.

Policy Options and Public Comment

Seven policy options were provided for consideration. Comments were received from 265 individuals and 9 organizations. Of the 265 individuals submitting comments, 151 were Virginia residents, 80 were out-of-State individuals, and 34 were of unknown residence.

95 percent of comments received were one of four form letter comments:

- Form letter #1 supported policy option #2 (in addition to taking positions on other policy options)
- Form letters #2, 3 and 4 opposed policy option #2 (in addition to taking positions on other policy options)

Comments were received by the following organizations

Form letter #1:

- Howard Rosenblum, Chief Executive Officer, **National Association of the Deaf (NAD)**
- Board of Directors (unsigned), **Virginia Registry of Interpreters for the Deaf (VRID)**

Form letter #3:

- Lisa Christensen, President, **American Academy of Audiology (AAA)**[1]
- Donna Sorkin, Executive Director, **American Cochlear Implant Alliance (ACIA)**
- Barbara Kelley, Executive Director, **The Hearing Loss Association of America (HLAA)**[2]
- Julia Bellinger, Manager, Government Affairs, **International Hearing Society (IHS)**

Non-form letters:

- Shari B. Robertson, President, **American Speech-Language-Hearing Association (ASHA)**
- Hilary Piland, Public Policy Manager, **Virginia Association of Community Services Boards (VACSB)**
- Samantha Marsh Hollins, Assistant Superintendent Department of Special Education and Student Services, **Virginia Department of Education (VDOE)**

Non-form letter comments were received by the following individuals

- Judy Alonzi
- Vicki Harrington
- Anne Hughes
- Renee Maxwell
- Leah Muhlenfeld
- Deborah Pfeiffer
- Gianina Thornton
- Jacob Thornton
- Irene Schmalz
- Joan Franklin (Out-of-State)
- Vicki Harrington (Out-of-State)
- Elizabeth Weyerhaeuser (Out-of-State)

[1] American Academy of Audiology's comments did not adopt the exact same language as form letter #3 but was substantively similar.

[2] HLAA's comments did not adopt the language of form letter #3 but supported recommendations made by AAA and ACIA

Overview of Comments

Comments	Individuals	Organizations	Of individuals, # comments:		
			In-State	Out-of-State	Unknown residence
Form letter #1	236	2	127	76	34
Form letter #2	10	0	10	0	0
Form letter #3	5	4	4	1	0
Form letter #4	2	0	2	0	0
Other comments	11	3	8	3	0
Total	**265**	**9**	**151**	**80**	**34**

Policy Option	Support	Oppose

 **13-0**
Option 1: Take No Action
	• Form letter #3[3]
	  • Includes: **AAA, ACIA, HLAA, IHS**
		• Form letter #1
		  • Includes: **NAD, VRID**
		• Form letter #2
		• Deborah Pfeiffer
		• Jacob and Gianina Thornton

Option 2: Introduce legislation and budget amendment based on SB 1741 with the following modifications:	• Form letter #1 (with modifications noted below)
	  • Includes: **NAD, VRID**
	• Deborah Pfeiffer
	• Joan Franklin (Out-of-State)
	• Elizabeth Weyerhaeuser (Out-of-State)
		• Form letter #2
		• Form letter #3
		  • Includes: **ACIA, HLAA, IHS**
		• Form letter #4
		• Anne Hughes
		• Leah Muhlenfeld
		• Irene Schmalz

• Define terms, including: language, communication modality, English, deaf or hard of hearing	• Comments in form letter #1, Jacob and Gianina Thornton: include ASL	

[3] Support for policy option #1 stated as a 1st preference. However, form letter #3 also supports other policy options.

Policy Option	Support	Oppose
• Change agency assigned to lead the implementation of SB 1741: from DBHDS to VSDB, in coordination with DBHDS, VDOE and VDDHH	• Comments in form letter #1: change to VDDHH	
• Change requirements for constitution of Advisory Committee: stipulate that VSDB will: 1) Determine size of Advisory Committee; 2) Ensure balanced membership in terms of: individuals who have expertise in the assessment/instruction of ASL, spoken English, English with visual supports, literacy; parents of children who are deaf or hard of hearing; individuals who are deaf or hard of hearing and those who are not		
• Stipulate that Parent Resource should be based on pre-existing resource guides	• Comments in form letter #1: must include better balance between English and ASL	
• Change basis of milestones away from "standardized norms": Base milestone selection on currently available assessments that are appropriate for evaluating progress toward age-appropriate language, including American Sign Language, Spoken English, and English literacy		
• Require that milestone data include additional characteristics of assessed children that can best inform agency-level programming, as determined by VSDB and coordinating agencies	• Form letter #1 • Includes: **NAD, VRID**	

Option 3: By letter of the JCHC Chair, request that VDOE conduct an analysis of literacy outcomes of children diagnosed with hearing loss, based on linking: a) existing VDOE literacy data collected for the pre-k level and higher with; b) VDH Early Hearing Detection Intervention (EHDI) hearing diagnosis data (contingent upon availability of VDH data in the Virginia Longitudinal Data System [VLDS]). A written report, which includes results of the analysis and recommendations for establishing a process for annual	• Form letter #2 (if tracked by modality, age of access to chosen modality, age of implantation, access to ASL models, etc.)
	• **ASHA**
	• Deborah Pfeiffer
	• Jacob and Gianina Thornton
		• Form letter #1
		  • Includes: **NAD, VRID**
		• Form letter #3
		  • Includes: **ACIA, HLAA, IHS**
		• Form letter #4
		• Leah Muhlenfeld

Policy Option	Support	Oppose
reporting by VDOE on literacy of children diagnosed with hearing loss based on existing literacy data, is to be submitted to the JCHC by October 31, 2020.		

Option 4: By letter of the JCHC Chair, request that VCU, in consultation with VDDHH, VDH, VDOE, and VSDB, incorporate language development milestones into or as an addendum to current and future versions of Virginia Resource Guides for Families of Children with Hearing Loss ("Green" and "Orange" guides). Incorporation of language development milestones should include establishing a formal process for stakeholder input on milestone selection and non-milestone information to be included in future Resource Guide(s). A report written by VCU, with VDDHH, VDH, VDOE, and VSDB input, is to be submitted to the JCHC by October 31, 2020.	• Form letter #2
	• Form letter #3
	  • Includes: **AAA, ACIA, HLAA, IHS**
	• Form letter #4 (with alternate suggestion)
	• **ASHA**
	• Judy Alonzi (with alternate suggestion)
	• Leah Muhlenfeld
	• Deborah Pfeiffer
	• Jacob and Gianina Thornton
		• Form letter #1
		  • Includes: **NAD, VRID**

Option 5: By letter of the JCHC Chair, request that VSDB coordinate with DBHDS, VDDHH, VDOE, and VDH to ensure that information on hearing loss and relevant services made available by State agencies to parents of D/HH children 0-5 years old is comprehensive in scope and consistent in content regardless of each agency's specific areas of focus. A report written by VSDB, with input from DBHDS, VDDHH, VDOE, and VDH, is to be submitted to the JCHC by October 31, 2020.	• Form letter #1 ("in combination with policy options 2 and 7")
	  • Includes: **NAD, VRID**
	• Form letter #2 (concerns about VSDB as coordinating agency)
	• Form letter #3 (concerns about VSDB as coordinating agency)
	  • Includes: **AAA, HLAA, IHS**
	• Form letter #4 (ensure comprehensive involvement in decisions with service provision organizations)
	• Leah Muhlenfeld
	• Deborah Pfeiffer
	• Joan Franklin (Out-of-State)
	• Elizabeth Weyerhaeuser (Out-of-State)
		• **ACIA**

Policy Option	Support	Oppose

Option 6: Introduce budget amendment (language only) requiring that DMAS work with DBHDS to provide Medicaid reimbursement for Early Intervention (EI) services delivered by telepractice. A report written by DMAS with DBHDS input – submitted to the JCHC by October 31, 2020 – should provide a timeline for Medicaid reimbursement for EI services delivered by telepractice and identify any necessary enabling legislation, funding, regulatory or other changes to meet that timeline.	• Form letter #2
	• Form letter #3
	  • Includes: **AAA, ACIA, HLAA, IHS**
	• Form letter #4
	• **ASHA**
	• **VACSB**
	• Leah Muhlenfeld
	• Deborah Pfeiffer
		• Form letter #1
		  • Includes: **NAD, VRID**

Option 7: Introduce budget amendment (language only), requiring VDDHH, in consultation with DMAS, DBHDS, VDOE, VDH and VSDB, to explore opportunities to develop programs connecting families of D/HH children with D/HH adults – including mentoring programs by Deaf adults or other models – with the goal of increasing uptake of EI services by families and providing assistance to families in sign- and non-sign-based communication. A report written by VDDH, with input from DMAS, DBHDS, VDOE, VDH and VSDB – to be submitted to the JCHC by October 31, 2020 – should provide a timeline for implementing programs to increase access to ASL instruction or, if barriers to doing so exist, identify any necessary enabling legislation, funding, regulatory or other changes required to address those barriers.	• Form letter #1 ("in combination with policy options 2 and 5")
	  • Includes: **NAD, VRID**
	• Form letter #2 (if programs increase family support)
	• **ASHA** (if Deaf Mentors include D/HH Individuals who use ASL, spoken language or combination of communication options)
	• Deborah Pfeiffer
	• Jacob and Gianina Thornton
	• Joan Franklin (Out-of-State)
	• Vicki Harrington (Out-of-State)
	• Elizabeth Weyerhaeuser (Out-of-State)
		• Form letter #3
		  • Includes: **ACIA, HLAA, IHS**
		• Form letter #4
		• Leah Muhlenfeld

Content of form letters

Form letter #1

I am writing to you as a [Deaf Adult/Deaf Advocate/Deaf Professional/ASL Interpreter/Teacher of the Deaf/Family Member] for Deaf children.

Thank you for taking the time to study SB 1741 – Language Development Milestones and Parent Resources for Young Deaf/Hard of Hearing Children (hereafter 'Deaf'). I would ask that you take the following action on the policy recommendations made by Andrew Mitchell, Senior Health Policy Analyst.

Policy Option 1 – **Please vote no to taking no action. Choosing policy option one, will continue the status quo of systematic language deprivation of Deaf children.**

Policy Option 2 – **Please vote yes to introduce legislation and budget amendments based on SB 1741 with the following modifications**

- Define terms, including: language, communication modality, English, deaf or hard of hearing ***Must include a definition of ASL as well.**
- Change implementing agency: provide **VDDHH*** primary implementation authority, in coordination with DBHDS, VDOE and **VSDB*.**
- Change requirements for constitution of Advisory Committee: stipulate that **VDDHH*** will:
    - 1) Determine size of Advisory Committee;
    - 2) Ensure balanced membership in terms of: individuals who have expertise in the assessment/instruction of ASL, spoken English, English with visual supports, literacy; parents of children who are deaf or hard of hearing; individuals who are deaf or hard of hearing and those who are not
    - Stipulate that Parent Resource should be based on pre-existing resource guides ***But that it must be updated to include a better balance between Languages: English and ASL. (Currently ASL guide is a separate publication and is not always given to parents of the Deaf.)**
    - Change basis of milestones away from "standardized norms". ***Standardized norms are available from the Ski-Hi Program in Florida and from the California Schools for the Deaf**
    - Require that milestone data include additional characteristics of assessed children that can best inform agency-level programming, as determined by VSDB and coordinating agencies ***We support this demographic data collection on Deaf children regardless of how many disabilities they may have.**

Policy Option 3 - Please vote **no** on policy option 3. **The analysis on literacy outcomes for children who are Deaf/Hard of Hearing should already be in practice. An analysis of literacy alone is insufficient - the concern here is the full acquisition of the child's first language, as a foundation for English literacy. This does not address the need for VDOE to select milestones for use in assessing Deaf/Hard of Hearing children's acquisition of ASL**.

Policy Option 4 - Please vote **no** on policy option 4. **It is insufficient for the state to only incorporate language development milestones into or as an addendum to current and future versions of Virginia Resource Guides for Families of Children with Hearing Loss. Professionals in the field of Early**

Intervention and Early Childhood Education must be training on assessing these milestones and data must be collected to ensure state accountability for the language acquisition of Deaf/Hard of Hearing children.

Policy Option 5 - **Policy option 5 is only appropriate if it is selected in combination with Policy Options 2 and 7. It is unfortunate that the state agencies that serve Deaf/Hard of Hearing children do not already collaborate to ensure that information on hearing loss and relevant services made available by State agencies to parents of D/HH children 0-5 years old is comprehensive in scope and consistent in content regardless of each agency's specific areas of focus.**

Policy Option 6 - Please vote **no** on policy option 6. **ASL is a visual, tactile language. Physical touch is required for teaching ASL to a Deaf/HH child, especially during the critical language years (birth to five years old). Physical touch is used to model the sign location on the child's body and to teach the appropriate sign movement and handshape. At times, when communicating in American Sign Language, physical touch is required as an attention getting technique, especially for young children. Due to the tactile and visual nature of ASL/Deaf Culture, telepractice is not 100% accessible for Deaf children (especially from birth to three years old). 'In-Person' language modeling that allows for physical touch is necessary for effective language exposure and adequate language acquisition.**

Policy Option 7 - Please vote **yes** on policy option 7 in combination with Policy Options 2 and 5. **Virginia is in desperate need of programs that connect families of D/HH children with D/HH adults - including mentoring programs by Deaf adults. Virginia is also in need of programs that increase access to ASL instruction for families with D/HH children. These programs are sorely needed, but do not alone address the issues raised in SB 1741. We ask that you please vote yes on policy option 7 in combination with recommending legislation and budget amendments based on SB 1741.**

Thank you for your attention and consideration of this critical issue in Virginia. We look forward to seeing the positive impacts that Policy Options 2, 5, and 7 (in combination) will bring to Deaf/Hard of Hearing children in Virginia!

Form letter #2

Thank you for your time and consideration of my comments on the Language Development Milestones and Parent Resources for Young Deaf/Hard of Hearing Children policy options. I am a parent of a deaf young man, a Cued Language Transliterator, and a member of the Northern Virginia Cued Speech Association, and I have an interest in the decision of the Commission.

I was appalled that the report produced by the Virginia Joint Commission on Health care completely ignored evidence that Cued Speech provides access to spoken language on the level that of received by typically-hearing children, even for profoundly deaf children who may receive limited benefit from hearing technology. Severely to profoundly deaf/hard-of-hearing children (D/HH) who use Cued Speech score as well as hearing children using the Developmental Sentence Score for expressive language (Berendt, et al 1990). This is because Cued Speech conveys spoken language visually; research shows that even profoundly deaf Cued Speech users have near-perfect visual reception of spoken language (Uchanski, et al 1990). Cued Speech is also linked to consistent, positive literacy outcomes for D/HH children, with or without hearing technology. For example, Illinois School for the Deaf found that where, nationally, D/HH children can expect a 2-month academic gain in a single school year, students whose IEP included cued English as the mode of instruction could demonstrate a 1-2 year academic gain in a single school year (Giese 2016). Furthermore, in Minnesota's school district #917, literacy gains among deaf cuers were also 1 year in a single school year (Kyllo 2010). And, as the Commission's report pointed out, English literacy is the universal measure of language among all American deaf/hard-of-hearing populations.

Cued Speech is the only modality that provides D/HH children complete access to the spoken language of their home, regardless of how well they are able to use hearing technology. For instance, cueing families in Virginia use cued Arabic and cued Hebrew, and the Northern Virginia Cued Speech Association is offering workshops this fall in cued Spanish. Research shows that D/HH children gain the most language when they have access to the language of the home via Cued Speech, in addition to cued English at school (Hage, C. et al 1989).

Moreover, the Commission is ignoring entire Virginia school districts and Virginia families who have chosen to use cued language via the Cued Speech system at home, at school, or both, including those in: Fairfax County, Prince William County, Arlington County, Stafford County, and the city of Williamsburg.

Before stating my positions in support of or against the Commission's proposed policy options, I urge the Commission to keep oversight or management of a policy on children who are deaf and hard of hearing within the Department of Behavioral Health & Developmental Services (DBHDS) in coordination with other agencies within the Virginia Early Hearing Detection and Intervention system. The recommendation for the Virginia School for the Deaf and Blind (VSDB) to have oversight over the development of policies and resources will not effectively serve the needs of all children and families. VSDB serves children whose primary language is American Sign Language (ASL) and the school personnel have limited knowledge and resources to serve children who use spoken language with or without Cued Speech, which comprise the majority of children with hearing loss in our state and around the country. Most infants and young children with permanent hearing loss use Listening and Spoken Language (LSL) (60-70%), 10-15% use Cued Speech, and 6-9% use American Sign Language (ASL) (White, K. R. 2018).

The VSDB does not have an oral program for those who choose to use LSL, and the VSDB does not support the use of Cued Speech to provide access to spoken language. In contrast, DBHDS and the Virginia Department of Education (VDOE) staff have expertise in, and access to, the full range of all

options and communication modals such as LSL, Cued Speech, Total Communication, ASL, and the language of the home if not English (Spanish, Korean, etc.).

Regarding the proposed Policy Options:
I support:

- Option Four. It is logical to incorporate language milestones into current VCU resource guides.
- Option Six. Medicaid covering early intervention services via telepractice would benefit many of Virginia's children, not just those who are D/HH. Lack of transportation or long distance is a hindrance for all types of therapy (speech, physical, occupational).

I support, with qualification:

- Option Three. I fully support this option, only if the data collected to track D/HH children's literacy in Virginia is in a format to support meaningful interpretation i.e. tracked by modality, age of access to chosen modality, age of implantation, access to ASL models, etc. This means VDOE must consult experts in the Virginia Early Hearing Detection and Intervention (EHDI) system, to include the Northern Virginia Cued Speech Association.
- Option Five. It is important for parents and families to have access to all unbiased information. The agencies listed are already involved in the updating and dissemination of resources. I reiterate concerns about the School for the Deaf having oversight over State agencies.
- Option Seven. I support expansion of D/HH mentorship opportunities—but only if D/HH mentors are matched with families to support the family's language goals. Furthermore, providing a timeline for "implementing programs to increase access to ASL instruction" does not support the mission of existing federal legislation, which is to protect the rights of children with disabilities and their families. Programs must increase family support, which includes access to all resources, not just ASL instruction.

I do not support:

- Option One. Taking no action is not an option unless agencies and service providers are held accountable by Virginia laws and regulations to build on existing resources; ensure fair, balanced representation of Cued Speech in resources; and treat D/HH children who use Cued Speech as distinct groups when tracking literacy and language outcome data. The National Center for Hearing Assessment and Management reported in 2018 that families reported receiving the lowest quality information about Cued Speech compared to other options like LSL, Total Communication, or ASL (White, K.R. 2018). There is room for improvement within the state EHDI systems to provide higher quality information about Cued Speech to families.
- Option 2. The reintroduction of another bill for the fourth year in a row on this issue is a distraction from ongoing improvements.

Form letter #3

Thank you for your time and consideration of my comments on the Language Development Milestones and Parent Resources for Young Deaf/Hard of Hearing Children policy options. I am a parent and have an interest in the decision of the Commission.

[Personalized content about individual background and perspective]

Before commenting on the policy recommendations, I would like to urge the Commission to keep oversight or management of a policy on children who are deaf and hard of hearing within the Department of Behavioral Health & Developmental Services (DBHDS) in coordination with the other agencies. The recommendation for the Virginia School for the Deaf and Blind (VSDB) to have oversight over the development of policies and resources will not effectively serve the needs of all children and families. VSDB serves children whose primary language is American Sign Language (ASL) and the school personnel have limited knowledge and resources to serve children who use spoken language, which comprise the majority of children with hearing loss in our state and around the country. Most children have mild to moderate hearing loss and function well with technology and listening and talking. Most infants and young children with permanent hearing loss use Listening and Spoken Language (LSL) (60-70%), 10-15% use Cued Speech, and 6-9% use American Sign Language (ASL) (White, K. R. 2018).

The VSDB does not have an oral program for those who choose to use LSL. Their emphasis is on meeting the needs of children with profound hearing loss and/or blindness who have chosen to make limited use of 21st century technology—hearing aids and cochlear implants. In contrast, DBHDS and the Virginia Department of Education (VDOE) staff have expertise in, and access to, the full range of all options and communication modals such as LSL, Cued Speech, Total Communication, ASL, and the language of the home if not English (Spanish, Korean, etc.).

The report contains outdated and erroneous statements. The report referenced a since debunked 2000 study that median reading ability of D/HH 12th graders is at 4th grade level; 10% with age-appropriate language skills. Not only does this statement combine all types of hearing loss into one category, it ignores numerous more recent studies that show quite the opposite, especially for those children who are implanted around 12 months of age. These include the Dettman et. al, 2013; Dornan et al., 2010; Geers 2011, and Nicholas 2007 peer reviewed studies.

Moreover, the report states that children with a CI do not obtain age level language development due to "underlying disability". In fact, the 2017 Geers study found that over 70% of children who received cochlear implants at an early age and did not use sign language achieved age-appropriate spoken language.

I support:

- Option One. Taking no action is the simplest due to improvements already underway by the VDOE and forthcoming changes to resources. Additionally, a continued legislative battle distracts from implementing current and future improvements to the system.
- Option Four. As there are milestones developed or being developed, it is logical to incorporate them into the current VCU resource guides.
- Option Five. It is important for parents and families to have access to all unbiased information. The agencies listed are already involved in the updating and dissemination of resources. I reiterate concerns about the School for the Deaf having oversight over the other agencies with

long and robust experience in educating and working with children across the scope of hearing loss.

- Option Six. Medicaid covering early intervention services via telepractice –would benefit many of Virginia's children, not just those who are deaf and hard of hearing. Lack of transportation or long distance is a hinderance not only for all types of therapy (speech, physical, occupational).

I do not support:

- Option 2. The reintroduction of another bill for the fourth year in a row on this issue is a distraction from ongoing improvements.
- Option 3. As the state already tracks literacy within the school system, Option Three is unnecessary and introduces confusion as to the difference between language and literacy.
- Option 7. If the Board were to consider Option 7 and a deaf mentor program, it must ensure that all forms of communication and parent choices are supported. The EHDI Act of 2017 supports programs and systems that "foster family-to-family and deaf and hard hearing consumer-to family supports" and makes no mention of a Deaf mentor program. Referencing a "Deaf" mentor program does not satisfy the need for options across the continuum including mentors with varying levels of hearing loss and diverse ways of communicating—including spoken language. I do not support Option 7 as currently described.

Thank you again for your time and consideration of this matter.

Form letter #4

[Personalized content about individual background and perspective]

In order to be respectful of your busy schedule, I have provided the policy options I feel may assist Virginia in improving systems, and which I feel would be extremely detrimental to current and future families of children with hearing loss.

WE SUPPORT

Policy Option 1 Take No Action

Justification: The mandates put forth in this bill are ones that are suggested by the LEAD-K national organization in California. The Commonwealth of Virginia already provides resources for children with hearing loss and their educators, we already follow developmental hierarchies for normal development for all children with disabilities, and we are in compliance with the federal and state mandates that require ongoing assessment and recommendations for children with hearing loss. We have problems with service provision for children with hearing loss in our state, but we need to empower our state agencies to make the needed improvements. This bill will not address or solve those problems. Instead, it will only financially-burden our already-struggling state agencies with activities and tasks that do nothing to solve the actual problem.

Policy Option 4 Incorporation of Language Development Milestones

Justification: We support with an alternate suggestion. Developmental milestones for children who do not have hearing loss already been fully-established and numerous resources are readily available which include them. Based on discussions during the workgroup meetings, a resource including ASL milestones has also been developed, but is constantly evolving. Although we do not have opposition to including them, we have two issues that should be considered:

1. If resources are already published and available for language development milestones, would it be more cost-efficient to purchase one of these resources versus add them to the resource and pay additional publication fees for additional printing;

Developmental Norms for Speech and Language
https://www.asha.org/slp/schools/prof-consult/norms/

If ASL developmental milestones exist but are still being developed, would it be more cost-efficient to also purchase this accepted resource (VCSL) and provide the most recent version to families? Otherwise, if new editions become available and a new state resource is not due for updating, we would be providing families with an outdated version until a new Resource Guide can be updated and financed.

The Standardized Visual Communication and Sign Language Checklist for Signing Children (VCSL)
Laurene Simms, Sharon Baker, M. Diane Clark
Sign Language Studies, Volume 14, Number 1, Fall 2013, pp. 101-124
Published by Gallaudet University Press DOI: 10.1353/sls.2013.0029

Policy Option 5 Assignment of VSDB as the Coordinating Agency

Justification: We support with qualification. If VSDB is to become the coordinating agency for this project, other state education agencies and programs charged with service provision for children with hearing loss must be comprehensively involved with any decisions made. We believe this is necessary because:

1. Residential schools for the deaf have historically been the home of individuals who claim membership in Deaf culture, where the primary language used is American Sign Language. Recently, these schools have attempted to embrace as bilingual-bicultural approach that claims to teach ASL and English, but this philosophy still does not include oral methods of communication, including listening and spoken language and Cued Speech. As one of the oldest schools for deaf in the country, VSDB's history and current culture is synonymous with this philosophy. There are no employees or programs at VSDB that are qualified or appropriate for any child whose family has chosen an oral method for language development for their child. As such, other agencies must be involved to maintain unbiased and equitable program development;
2. Only statewide programs, such as DBHDS (Early Intervention) and VDOE, have the reach to ensure that any recommendations made will be able to be rolled out across the state. VSDB only has jurisdiction on their campus.

Policy Option 6 Budget Amend. Requiring DMAS to Review Reimbursement for Telepractice

Justification: Due to the lack of qualified professionals statewide and the financial and physical obstacles that are very real deterrents for many families seeking appropriate intervention for their child, telepractice is the service provision vehicle for the present and future. Much research has provided evidence of its effectiveness and its ability to bring much-needed services to individuals who would otherwise not have access to them

WE DO NOT SUPPORT

Policy Option 2 Legislation and Budget Amendment

Justification: This bill will not address or solve the problems we have with service provision for children with hearing loss in Virginia. Instead, it will only financially-burden our already-struggling state agencies with activities and tasks that do nothing to solve the actual problem. None of the proposed changes will affect the system-wide change necessary to improve outcomes of these children.

Furthermore, the development and process for passing this highly-controversial bill will prove to bog down the legislative process for the fourth year in a row and distract from the actual issues we should be working to improve.

Policy Option 3 Analysis of Literacy Outcomes

Justification: An accurate analysis of literacy outcomes of all children with hearing loss is impossible without a completed overhaul of the current data collection system. Review of past data would only deliver data that is incomplete, skewed and misrepresentative. One cannot make any valid decisions based upon invalid data.

As mentioned previously, many children who use listening and spoken language reach age-appropriate levels of language and literacy early in their school years. As such, they are no longer tracked by the Individualized Education Plan (IEP). Because of this, their scores are assimilated into the Standards of Learning assessments and not separated from the rest of the student population.

Policy Option 7 Deaf Mentor Program

Justification: At this juncture, there is no language in federal or state mandates that endorses a Deaf mentor program, which is inherently biased and inequitable to all other languages and communication methods due to its designation of "Deaf" as a cultural reference. Currently, many listening and spoken language families receive support through personal contacts made through professional connections or

through support groups or social media. It seems that, if a list of resources for Deaf mentors should be developed and housed, it should be through VSDB. This school has access to generations of their graduates who may be willing to meet and be involved in the lives of children who use ASL. This does not seem to be a need necessary of a state budget amendment, when the need can be satisfied through other existing means.

It is my hope that this Commission will ensure the best possible outcomes for children with hearing loss by supporting current state agencies and by making sure these children have access to the healthcare that allows for the best possible outcomes for these children.

Increased Prescription Delivery Options at Same Cost for Health Plan Members

Andrew Mitchell, ScD
Senior Health Policy Analyst

Study Mandate

House Bill 2223 (Delegate O'Quinn) would have required health plans/Pharmaceutical Benefits Managers (PBMs) to permit filling of mail order prescriptions at network participating retail pharmacies: with retail pharmacies reimbursed at "comparable" price to mail order, calculated on the same basis; without imposing differential patient copayment, fee, condition. The bill was Passed By Indefinitely in Senate Committee on Education and Health and sent to the JCHC for consideration.

Background

House Bill 2223 is a type of "Any Willing Provider" (AWP) law focused on channel of distribution (i.e., mail order vs. retail). Virginia Code contains two sections relevant to the bill. First, Virginia's "Freedom of Choice" Act (§§38.2-3407.7, 38.2-4209.1, 38.2-4312.1) allows patients to select any non-network pharmacy to receive pharmacy benefits – with the same patient-side conditions as when receiving benefits from network pharmacies – as long as the non-network pharmacy signs a contract that insurer requires of all network pharmacies (the insurer must reimburse the non-network pharmacy at the network rate). However, insurers are permitted to select a single mail order provider as their exclusive provider of mail order pharmacy services. Second, retail pharmacies are allowed to dispense by mail order on limited basis/as an "ancillary service" (§38.2-3407.15:4). Determination of what constitutes an ancillary service vs. something more than ancillary is made via contract between the PBM/carrier and pharmacies.

In the context of Pharmaceutical Benefit Manager (PBM) services, HB 2223 is focused on addressing potential conflicts of interest. Direct pharmacy dispensing – by mail order and/or specialty services – is a common part of services provided by PBMs. PBM-affiliated mail order dispensing may create a conflict of interest, such as by incentivizing the use of mail order pharmacies regardless of benefit to plan sponsor or patient. While a 2005 study by the Federal Trade Commission (FTC) found that mail order pharmacy ownership by PBMs "generally did not disadvantage plan sponsors", the applicability of those findings in current markets is not known. In 2014, the FTC commented on the "need for continued analysis of potential misalignment of incentives or conflicts of interest" in pharmacy plan design as part of a letter to the Center for Medicare & Medicaid Services (CMS).

Key Considerations on House Bill 2223

Potential cost and quality impacts

The impact of HB 2223 on future prescription costs is likely to depend on changes in mail order market concentration and inherent cost differentials between mail order/retail pharmacy-filled prescriptions. In

a highly concentrated market – such as when there is an exclusive provider of mail order services – economies of scale may help contain costs, such as by giving PBMs leverage to negotiate larger rebates from manufacturers and price concessions from pharmacies due to a high and/or predictable volume of prescriptions. Opening up the mail order market to any willing pharmacies could fracture the market and drive up prices, through either reduced manufacturer rebates or higher fees paid to pharmacies. However, there are reasons that the impact of opening up the mail order channel on market concentration/prices may be limited. First, there may be very little, if any, demand for additional options to receive mail order-covered services: members of many health plans can already fill mail-order covered prescriptions for the same patient contribution at brick-and-mortar pharmacies through "Retail 90" networks, and, since 2018, the Bureau of Insurance has received no complaints of any kind from consumers related to pharmacy benefits. Second, other States' experiences with AWP laws focused on mail order channel suggest that there are limited changes in market concentration when retail pharmacies are required to meet mail order terms and conditions. Likely many retail pharmacy owners determined that the costs associated with meeting the mail order requirements negated the benefits.

HB 2223 could also impact quality of pharmaceutical benefits. Contracts between PBMs and pharmacies lay out both reimbursement price schedules and "terms and conditions" required for reimbursement. The terms and conditions are generally different between retail and mail order pharmacies and omission of a requirement for retail pharmacies to adhere to mail order "terms and conditions" could adversely impact quality of some mail order covered services. For example, specialty drugs, e.g. chemo-therapy pills, are required to be dispensed by mail order to ensure a) patient has 24/7 telephone access to pharmacists; b) adherence to storage, shipping and handling standards; and c) tracking of patient outcomes (Khandelwal et al., 2011). In HB 2223, there is no requirement for retail pharmacies to meet mail order terms and conditions.

Recommendation

- If legislation similar in intent to HB 2223 is considered: Include provision requiring retail pharmacies to adhere to same terms and conditions as pharmacies providing mail order services

Compliance

Ensuring compliance of HB 2223's provisions would require substantial changes in how the Bureau of Insurance (BOI) currently conducts oversight, and – without additional legislation – that oversight could be substantially limited. In particular, implementation of PBM/pharmacy-focused provisions by the BOI would require changes to its existing business practices because the BOI does not currently conduct contract and/or claims comparisons focused on PBM reimbursement prices and basis of costs. Additionally, PBMs are not currently required by law to provide information directly to the BOI because the BOI regulates carriers (not PBMs). Without additional legislation requiring that all relevant PBM records be provided to the Bureau, the BOI would be limited in its ability to ensure enforcement. Other States (e.g., Maine) addressing similar issues have passed legislation that could serve as a model for creating a stronger regulatory framework around PBMs. That approach requires that carriers have the ability to access – and make available to BOI – all data related to prescription benefits provision that would be needed to ensure that the BOI could obtain relevant data for enforcement (e.g., PBM drug transaction/pricing data). Such an approach would provide the BOI the necessary authority to ensure compliance with the provisions of HB 2223. To address potential legal challenges, legislation to this

effect should also ensure confidentiality of data provided by the PBM to the BOI to address anti-trust concerns or other legal challenges.

Recommendation

- If legislation similar in intent to HB 2223 is considered: Include provisions to license PBMs and require carriers to have ability to access/make available to BOI all data related to provision of prescription drug benefits

Additional Considerations

Vagueness in terminology and ambiguity in how certain sections of HB 2223 relate to each other should be addressed. First, a key component of the bill is to require retail pharmacies to be reimbursed at a "comparable" price to mail order, with that price calculated on the same basis between retail and mail order. Determining whether a retail reimbursement price is "comparable to" mail order price could be difficult. Second, the bill includes drug manufacturer rebates as a required component in determining that basis of the reimbursement price (along with direct and indirect administrative fees, costs and any remuneration). Although manufacturer rebates may indirectly affect reimbursement prices for mail order pharmacies – if those pharmacies are vertically integrated with PBMs – rebates are generally not passed on by the PBM or plan sponsor to pharmacies and therefore are not a direct input into prices. Finally, the bill contains a section requiring the same benchmark index to be used to reimburse all pharmacies. As it is written, that section is not tied to the bill's provisions on determining whether the price is comparable and could be interpreted as requiring all pharmacies across all networks to be reimbursed in a uniform way.

Additionally, as noted in the bill's Fiscal Impact Statement, HB 2223 is in conflict with the mail order exclusivity provision of Pharmacy Freedom of Choice Act, and there are certain prescriptions prohibited by federal law from dispensing from retail pharmacies (45 CFR 156.122). The bill would need to be amended to address those issues.

Recommendation

- If legislation similar in intent to HB 2223 is considered: 1) Require retail pharmacy be reimbursed a price "identical to" that of mail order, calculated to reflect all *direct* price inputs and based on the same benchmark index; 2) Eliminate mail order exclusivity provision from Pharmacy Freedom of Choice Act; 3) Exempt from provisions prescriptions federally prohibited from retail channel dispensing

Other Approaches to Addressing Possible PBM Conflicts of Interest

While HB 2223 focuses narrowly on addressing potential PBM conflicts of interest related to mail order vs retail channels, other States are increasingly addressing potential PBM conflicts of interest. These include:

- Anti-steering provisions, which prohibit PBMs from incentivizing in various ways the use of PBM-affiliated or –owned pharmacies
- Prohibiting reimbursement of non-PBM-owned/-affiliated pharmacies less than PBM-owned/-affiliated pharmacies for same service

- Including ownership-related factors in PBM reporting requirements (e.g., annual audits must report on differential payments to pharmacies based on ownership differences)

Recommendation

- JCHC members may wish to consider other or additional approaches focused on possible PBM ownership-related conflicts of interest, including legislation related to incentivizing patient choice, reimbursement differentials to pharmacies, and transparency reporting provisions.

Policy Options and Public Comment

Comments were received from the following organizations:

- Christina Barrille, Executive Director, **Virginia Pharmacists Association** (VPhA)
- R. Scott Woods, Assistant Vice President, State Affairs, **Pharmaceutical Care Management Association** (PCMA)

Policy Option	Support	Oppose
 **10-3** **Option 1**: Take No Action		
Option 2: Introduce legislation authorizing the Bureau of Insurance to license and regulate PBMs through insurance companies	• VPhA	• PCMA
Option 3: In conjunction with Option 2, introduce legislation based on HB 2223 that:	• VPhA (except where noted)	• PCMA
• Requires retail pharmacies to adhere to same terms and conditions as mail order		• VPhA
• Requires retail pharmacy be reimbursed a price "identical to" that of mail order, calculated to reflect all direct price inputs and based on the same benchmark index	• VPhA: change to "no less than"	
• Eliminates mail order exclusivity provision in Pharmacy Freedom of Choice Act		
• Exempts prescriptions federally prohibited from retail channel dispensing		
• Requires carriers to have ability to access/make available to BOI all data related to provision of prescription drug benefits		
Option 4: In conjunction with Option 2, introduce legislation that:	• VPhA	• PCMA
• Option 4a: Prohibits PBMs from incentivizing use of PBM-owned or -affiliated pharmacies		

Policy Option	Support	Oppose
• Option 4b: Prohibits PBMs from reimbursing non-PBM-owned/-affiliated less than PBM-owned/-affiliated pharmacies for the same/equivalent services • Option 4c: Requires PBMs to make available to carriers/BOI data necessary to determine whether aggregate pharmacy reimbursement differentials exist based on ownership status (through annual audit report and/or de-identified/confidential claims-level data)		

The Pharmaceutical Care Management Association highlighted its opposition to all Policy Options (except Take No Action) stating that: "PCMA opposed HB 2223 during the legislative session because the bill is unnecessary under Virginia's existing any willing provider (AWP) and Freedom of Choice (FOC) statute, would raise costs on Virginians who choose to use lower cost mail order pharmacies, and dismantle private contracting designed to keep costs low and improve quality by requiring that all pharmacies be reimbursed the same amount, regardless of cost or quality."

The Virginia Pharmacists Association highlighted its support for policy options #2 - 4 stating that: "VPhA believes there should be greater parity among prescription delivery options, which was the original impetus for HB 2223…Community pharmacies offer unique patient care benefits not available from mail order pharmacies. Each time a patient enters a pharmacy to pick up a prescription, they are in contact with a healthcare provider, who can offer counseling, advice, or recommend a needed vaccine. This convenient access to quality care benefits the individual patient and the community as a whole."

Naloxone Public Access and Storage

Andrew Mitchell, ScD
Senior Health Policy Analyst

Study Mandate

HJ 653 (Delegate Gooditis) requested the Virginia Department of Health (VDH) study barriers/solutions to co-locating naloxone in Automatic External Defibrillators (AEDs) and propose/implement an education program. The resolution was tabled in House Rules Committee with understanding that JCHC would consider a study in its 2019 workplan. A subsequent letter from Delegate Gooditis requested that JCHC focus on: whether removing barriers to administering naloxone is likely to save lives without causing significant damage to public health; whether/how naloxone can be placed in publicly accessible places, such as alongside AEDs.

Background

Naloxone hydrochloride is a short-acting opioid antagonist that has a high rate of success in reversing effects of opioid overdoses. Although naloxone is a Schedule VI Controlled Substance in Virginia, it is not scheduled federally by the Drug Enforcement Agency, is not psychoactive, has no effect in the absence of opioids, and has no abuse potential. Two FDA-approved formulations for community use include Narcan nasal spray and EVZIO auto-injector.

Recent legislation and agency initiatives in Virginia have focused on increasing public accessibility to naloxone. In the context of over 1,200 opioid overdose fatalities occurring annually in Virginia, legislation from the 2019 session eliminated a requirement that substance abuse-focused organizations obtain a Controlled Substance Registration for naloxone dispensing, as well as expanded the list of professionals authorized to possess, administer and dispense naloxone under a statewide Standing Order. (Currently, any individual may obtain naloxone from a pharmacist or one of 10 categories of professionals identified in §54.1-3408(X).) Board of Pharmacy protocols require authorized dispensers to provide some form of naloxone instruction and/or DBHDS' naloxone training REVIVE! brochure to lay individuals at the time of dispensing. In term of agency initiatives, over 23,000 naloxone kits have been procured by VDH for community-based distribution and, to date, around 35,000 individuals have received DBHDS REVIVE! training in opioid overdoses. Additionally, a recent VDOE Superintendent's Memo requires local school divisions to develop naloxone policies.

Naloxone Training and Education

While the act of administering naloxone is straightforward – studies have found high rates of successful administration of naloxone by untrained lay rescuers – and there are no special requirements for the storage or handling of naloxone, layperson training still may be necessary. Training and education on opioid overdose *recognition and response* – which usually accompanies training in naloxone administration – can be important to both improving patient outcomes (e.g., taking steps to avoid vomit-induced aspiration; calling 911 to ensure medical assistance) and ensuring lay rescuer's safety (e.g., being prepared for patient agitation from opioid withdrawal). In Virginia, DBHDS' REVIVE! training

is the primary channel that the public can access naloxone/opioid overdose training. While its current lay rescuer module takes 1 – 1.5 hours to complete, DBHDS has recently developed an abbreviated (7-10 minute) "Rapid REVIVE" in-person training model that targets high-volume events, high-risk groups, and treatment centers. DBHDS is also exploring a 10-15 minute online version for lay rescuers.

Lesser known channels of information on opioids include 911 call centers and regional Poison Control Centers (PCCs). In acute situations, 911 call centers with Emergency Medical Dispatch (EMD) services are potential sources of guidance/information on opioid overdose and/or naloxone administration. While some 911 call centers are currently integrating opioid overdose and/or naloxone administration protocols into Emergency Medical Dispatch (EMD) services, others are not yet doing so, and around 1/3 of 911 call centers don't offer EMD services. In acute or non-acute situations, PCCs – a confidential call-in resource staffed 24/7 by medical professionals – have expertise in opioid overdose response. However, PCCs are not widely known to the public as sources of information. Opportunities may exist to both build EMD capacities and leverage existing PCC capacities.

Recommendations on Naloxone Training and Education

- If JCHC members consider legislation on positioning naloxone in public places, retain training requirement for lay administrators
- JCHC members may wish to request stakeholders to investigate opportunities to strengthen emergency communications capacities in opioid overdose/naloxone administration and leverage existing capacities of regional Poison Control Centers in non-acute and/or acute situations

Naloxone Accessibility in Public Places[4]

A limited number of other States and localities have experience with positioning naloxone in public places to provide opportunities to lay rescuers to respond to opioid overdose emergencies. These include the Rhode Island "NaloxBox" program – in which organizations establish Memoranda Of Understanding with the State's Disaster Medical Assistance Team/Medical Reserve Corps – and positioning of naloxone in municipal or other buildings in three other States. To date, no instances of naloxone administration have been reported through these new programs.[5]

Co-locating Naloxone with AED Units

Co-locating naloxone with AED units may not be the most effective approach to expanding public accessibility of naloxone, especially given that there is no comprehensive database of AED locations in Virginia. Pros of co-located naloxone/AED units include public familiarity with AED units, the possibility of sudden cardiac arrest due to an opioid overdose, and existence of AED-related software/apps linking AEDs to first responders. Conversely, a program to co-locate naloxone with AED units may not be cost-effective, there may be a higher potential for theft of naloxone kits compared to AEDs, and there may be liability concerns with positioning naloxone – a Schedule VI Controlled Substance in Virginia – in publicly accessible AED units.

[4] For purposes of this study, "public place" is defined as any enclosed location that is used or held out for use by the public, whether owned or operated by public or private interests, and regularly staffed.

[5] 2017 is the earliest date of establishment of these programs.

Positioning Naloxone in Public Places

Positioning naloxone in public places could increase opportunities for lay rescuers to respond to some opioid overdose emergencies. On the one hand, naloxone positioned in public places is not likely to be the most effective strategy for the majority of opioid overdose fatalities, which take place inside the home (e.g., between 2016 and 2018, over 60% of fatalities occurred at home). Additionally, urban areas with the highest concentration of public places are also likely to have other sources of rapid access to naloxone (e.g., 911-dispatched first responders). On the other hand, positioning naloxone in public places could be an effective strategy when bystanders are hesitant to call emergency services (e.g., when illicit drugs are present) or when opioid overdoses are consistently clustered in certain areas (e.g., hotels).

In Virginia, data collected for this study indicate that approximately 50% of opioid overdose fatalities that occurred outside of home between 2016-2018 in three metropolitan areas took place in proximity to (within 1/10th mile of) a public place. Percentages of fatalities occurring most frequently in proximity to different types of public places is indicated in the table, below.

% overdose fatalities outside of home occurring within 1/10th mile of:

Location Type**	Richmond (n=260)	Hampton Roads (n=278)	Roanoke (n=55)
Eating establishment	15%	16%	16%
Gas station/convenience store	15%	13%	9%
Hotel	10%	20%	16%
Religious establishment	14%	13%	15%
Municipal/government building	9%	1%	0%
Pharmacy	7%	5%	5%

Availability of Naloxone in Community Pharmacies

Although VDH's Standing Order is intended to facilitate access by the public to naloxone – including through retail pharmacies – media reports and previous research indicate variability in the public's ability to obtain naloxone through the pharmacy channel. In a survey of a statewide representative sample of ~300 community pharmacies, 77% of pharmacies accurately indicated that a patient-specific prescription was not required to purchase naloxone. However, only 50% of *independent* pharmacies provided accurate information on obtaining naloxone without a patient-specific prescription (compared to 87% of chain pharmacies). Overall, ~65% of pharmacies had naloxone in stock at the time of contact for the survey.

Recommendations on Naloxone Accessibility in Public Places

- If JCHC members consider legislation on positioning naloxone in public locations, focusing on co-location with AED units may not be most effective strategy
- JCHC members may wish to consider legislation adding to the list of individuals explicitly authorized to possess and administer intranasal/intramuscular formulations of naloxone persons acting on behalf of public places who have completed a training program

- JCHC members may wish to request that the Board of Pharmacy re-emphasize in communications that Virginia law permits dispensing of naloxone without a patient-specific prescription

Supply-/Demand-Side Considerations

A variety of no-pay and discounted options exist to purchase naloxone. While typical cash prices for naloxone range from ~$120/kit (Narcan) to >$4,000/kit (EVZIO), the public can obtain VDH-procured naloxone at no-cost and/or through most health insurers for a co-pay. Narcan/EVZIO manufacturers currently have community/public pricing programs for qualifying organizations (e.g., Narcan: $75 for non-profit organizations; 2 kits at no cost for schools, YMCAs and libraries; EVZIO: $178/kit for government agencies, first responders, and "other qualifying groups"). However, survey data collected for this study suggest hesitancy by locality-managed public places to stock naloxone. In a survey of 58 locality/county administrators[6], only 30% indicated that their local government would be somewhat or very likely to consider stocking naloxone if authorized by Virginia Code. Major concerns expressed related to liability, employee training, costs and naloxone security/theft.

Additionally, current Virginia law related to naloxone possession and administration may be a deterrent to willingness to use naloxone in certain circumstances. Although Virginia Code provides Good Samaritan (civil) liability protections for naloxone administration by individuals who are dispensed naloxone under authorized channels, individuals may come to possess and administer naloxone in other ways. Possession through unauthorized channels is a Class 4 misdemeanor – up to $250 fine – and administration would not be covered by Good Samaritan liability protections. The limited applicability of liability protections could deter willingness of naloxone administration by individuals (e.g., in opioid overdose events involving illicit substances) and public places/organizations (e.g., to develop on-premise naloxone policies due to liability concerns stemming from individual-level liabilities). Broadening civil/criminal liability protection could diminish those deterrents.

Recommendations on Naloxone Accessibility in Public Places

- JCHC members may wish to consider legislation broadening criminal and civil liability protections for possession and administration of naloxone (e.g., regardless of channel naloxone was obtained)
  - Illustrative language: A person who is: 1) not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal and 2) acting in good faith, and in the absence of gross negligence or willful and wanton misconduct, may administer an opioid antagonist to another person who appears to be experiencing an opioid related drug overdose. The person administering naloxone or other opioid antagonist used for overdose reversal shall not be considered to be engaged in the unauthorized practice of medicine or the unlawful possession of an opioid antagonist. A person who administers an opioid antagonist pursuant to this article is personally immune from civil or criminal liability for any act or omission resulting in damage or injury.

[6] Response rate for all counties/localities was around 30%

Policy Options and Public Comment

Comments were received from the following organizations:

- Dean Lynch, Executive Director, **Virginia Association of Counties** (VACo)
- Janet Areson, Director of Policy Development, **Virginia Municipal League** (VML)

Policy Option	Support	Oppose
Option 1: Take No Action **4-9 FAILED**		
 **9-4** **Option 2**: Introduce legislation to amend §54.1-3408 by adding language authorizing persons acting on behalf of public places, who have completed a training program, to possess and administer intranasal / intramuscular formulations of naloxone in case of suspected overdose. For this section, "public place" is defined as any enclosed location that is used or held out for use by the public, whether owned or operated by public or private interests, and is regularly staffed.	• VML	
 **9-4** **Option 3**: Introduce legislation broadening criminal and civil liability protections for naloxone administration. Suggested language: A person who is 1) not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal and 2) acting in good faith, and in the absence of gross negligence or willful and wanton misconduct, may administer an opioid antagonist to another person who appears to be experiencing an opioid related drug overdose. The person administering naloxone or other opioid antagonist used for overdose reversal shall not be considered to be engaged in the unauthorized practice of medicine or the unlawful possession of an opioid antagonist. A person who administers an opioid antagonist pursuant to this article is personally immune from civil or criminal liability for any act or omission resulting in damage or injury. [Note: language developed with input from representatives of the Virginia Association of Commonwealth's Attorney, Virginia Criminal Justice Conference, and Virginia Trial Lawyers Association]	• VACo • VML	

Policy Option	Support	Oppose
 9-4 **Option 4**: By letter of the JCHC Chair, request that the Board of Pharmacy include information about Virginia laws making naloxone available without a patient-specific prescription in the next pharmacy profession license renewal communication		
 10-3 **Option 5**: By letter of the JCHC Chair, request that the HHR Secretary convene a task force to study current roles of Public Safety Answering Points (911 call centers) and regional Poison Control Centers in providing information/assistance to the public on opioid overdoses and naloxone in both acute and non-acute situations. A written report – submitted to the JCHC by October 31, 2020 – should provide recommendations on any necessary enabling legislation or funding that may be required to enhance their respective roles		

Both **the Virginia Association of Counties (VACo)** and the **Virginia Municipal League (VML)** highlighted concerns cited in the study's survey of localities to support Policy Option 3. VACo stated that: "Clear liability protections for an individual who administers naloxone, including local government staff, as well as for the entity making the naloxone available, would be essential prerequisites for localities to consider stocking naloxone in public facilities. We would encourage the Commission to **ensure that liability protections are included in any legislation** that might move forward authorizing the placement of naloxone in facilities owned or leased by local governments." **Additionally, VML indicated support for Policy Option 2**.

Forensic Nursing in the Commonwealth

Stephen Weiss, MPA,
Senior Health Policy Analyst

Study Information

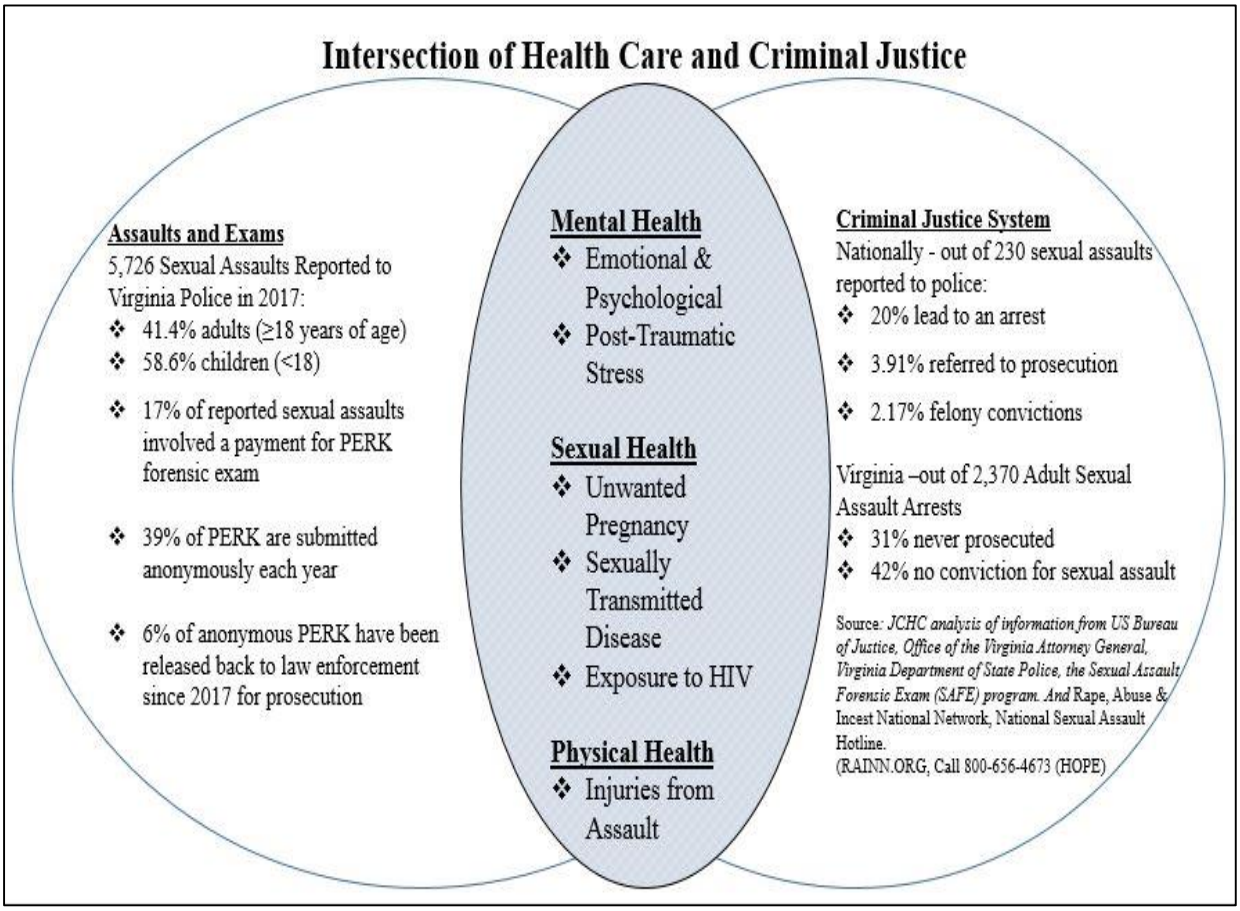
House Joint Resolution 614 (Delegate Delaney) requested that the Virginia State Crime Commission do a Forensic Nursing study. Due to time constraints, and with State Crime Commission member approval, the director asked the Joint Commission on Health Care (JCHC) to conduct the study. During the May work plan meeting, JCHC members approved the transfer of HJR 614 from the crime commission to the health care commission. Per Delegate Delaney's request, as written in the resolution, the JCHC study included: (i) a review of existing forensic nursing (FN) programs in Virginia; (ii) identification of regions of the state with no FN programs or nurses and the closest locations where FN services are provided; (iii) the current funding sources for existing FN programs, the cost to create new programs, including potential funding sources; (iv) the actual cost of evidence collecting and court testifying, identification of potential funding sources to cover the costs for FN testimony; (v) the current FN workforce and ways to increase availability of FN certifications to nurses; (vi) possible insurance reimbursement for FN services; and (vii) best practices in other state FN programs, including telehealth.

Background

Forensic nursing is a specific practice of nursing where the health and legal systems intersect. According to the International Association of Forensic Nurses (IAFN), "victims of violence and abuse require care from a health professional who is trained to treat the trauma associated with the wrong that has been done to them—be it sexual assault, domestic/intimate partner violence, neglect, or other forms of intentional injury." In addition, forensic nurses collect evidence and give testimony that can be used in the criminal justice system to apprehend and prosecute those who commit violent and abusive acts against others.[7]

Forensic nurses work in a variety of fields, including sexual assault (as Sexual Assault Nurse Examiners or SANEs), domestic/intimate partner violence, child abuse and neglect, elder abuse, death investigation, and corrections. The overwhelming majority of forensic nurses in Virginia work for hospitals in forensic nurse examination programs. The nurses are specially trained registered nurses credentialed to treat and examine victims of sexual assault. The JCHC study found that advocacy groups, law enforcement agencies, and the Commonwealth's Attorneys ask the forensic nurses for additional assistance with examinations of victims of the other types crimes, e.g. domestic/intimate violence, etc. These requests often lead to an expansion of the original forensic nurse examination program from sexual assault examinations to the other types of examinations related to violence and abuse. The study focuses on both forensic nurse examination issues and general issues related to forensic nursing programs.

[7] International Association of Forensic Nurses website (https://www.forensicnurses.org/page/WhatisFN)



Findings

Training – Needs to be standardized

Forensic nurse examiners (FNE) are registered nurses (RN) who are required to have two or more years of experience as an RN before they can become credentialed and/or certified as FNEs.[8] There are no recognized national standards for FNE training. The IAFN, US Department of Defense and the American Nurse Credentialing Center offer guidelines for FNE training. The guidelines include 40 hours of online course work that results in a certificate of completion followed by 40 hours of supervised clinical training with experienced forensic nurses. The supervised clinical training can last between 2 months to a year, or longer. While the online course work is available through several websites (e.g. Tribal Forensic Healthcare, IAFN), the supervised clinical training is only available where forensic nurse examiner programs exist.

The length of time to complete the clinical training depends on if the RN is full time, part time or PRN (as needed). In addition, each FNE program in Virginia has different supervised clinical requirements. Some require 10 pelvic exams while others require 50; some require the RN to attend court while others

[8] FNE are credentialed as Sexual Assault Nurse Examiners for Adults (A) and/or Pediatrics (P). The credentials are recognized by the American College of Emergency Physicians, Emergency Nurses Association, American Nurses Association, United States Department of Justice, State prosecutors, and Law Enforcement. In addition, a FNE can be certified in adult and/or pediatrics by the International Association of Forensic Nurses.

require RNs to accompany law enforcement officers as they respond to sexual assault calls. A JCHC survey of nurses and hospitals found that of the 93,902 licensed RNs in Virginia only 96 to 155 are recognized as FNEs. The lack of national standardized FNE training has led to at least seven states adopting their own standards by state law or administrative rule.[9]

Location of FNE Programs is Unclear – Require hospital referral protocols and identification of FNE programs

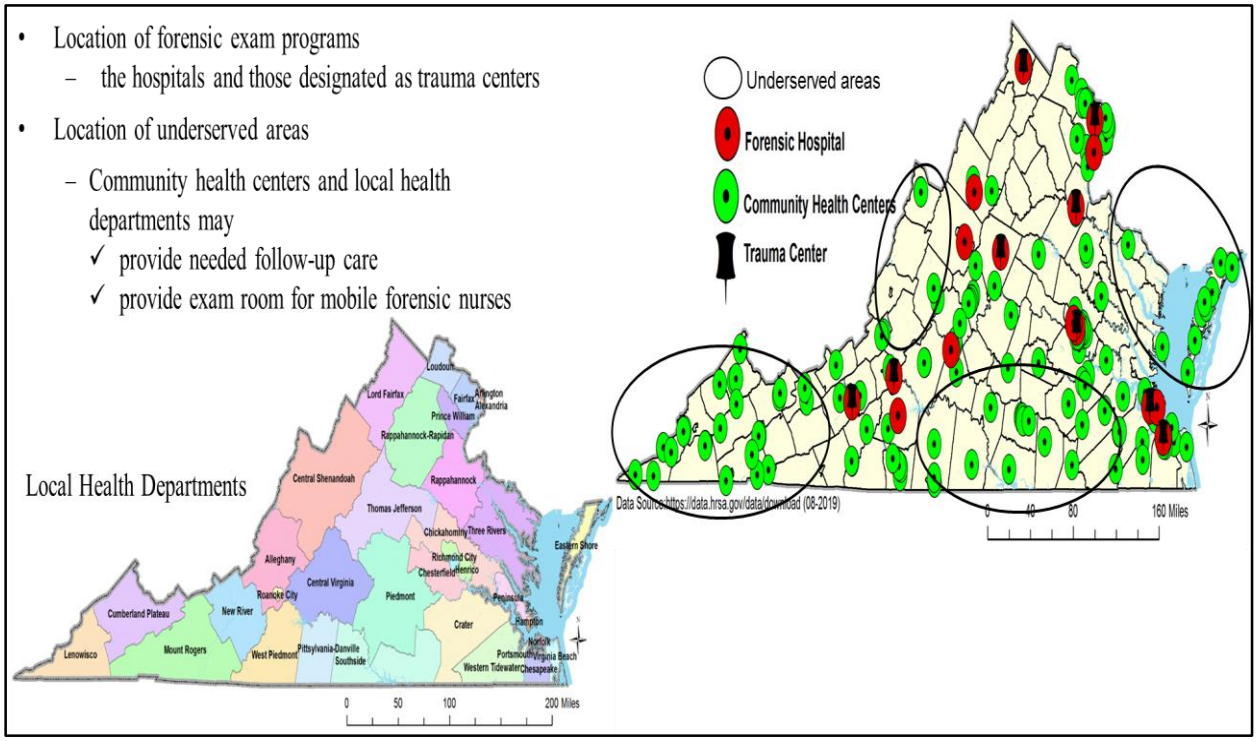
Knowledge of FNE programs in Virginia is based on an informal network of forensic nurses, Commonwealth's Attorneys and a list posted on the IAFN website. JCHC surveys and reviews of data indicate that only 16 of 122 hospitals, plus one mobile FNE program, provide FNE services in the Commonwealth. The lack of FNE programs in the state results in sexual assault victims driving for hours for a FNE exam and could involve traveling to 2 or 3 hospitals before locating one with an FNE available to provide the service. In addition, JCHC staff found that law enforcement and EMS providers also are turned away by hospitals that do not provide FNE services.

Follow-up exams – Other local and community health care providers should be involved in sexual assault response plans and included on the Sexual Assault Response Teams (SART)

Follow-up exams are an important and necessary part of any health care treatment plan, especially ones involving trauma, injuries, prevention of unwanted pregnancies and the possible existence of sexually transmitted diseases. For some patients, transportation back to the hospital where the initial exam was performed is not feasible. However, study findings indicate that follow-up referrals to a sexual assault victim's primary care physician often result in patient privacy concerns and confusion over the purpose of the appointment. The use of safety-net clinics is also problematic given that FNEs report difficulty locating these clinics and there appears to be a lack of knowledge about all of the different safety-net clinics in their area.

These issues could be partially addressed by including a range of providers, especially primary care physicians and providers from safety-net clinics, on SARTs. SARTs are created by Virginia Code § 15.2-1627.4 and led by Commonwealth's Attorneys. They are required to meet annually to develop a comprehensive and trauma-informed response for sexual assault victims within the Commonwealth's Attorney's jurisdiction. SART team members are listed in Virginia Code and include forensic nurse examiners or health care providers that perform Physical Evidence Recovery Kits (PERK), if any of those health care providers exist within the Commonwealth's Attorney's jurisdiction. The current Virginia Code does not include local hospital administrators, local health department district directors, representatives of safety-net clinics, or other local health care providers. As a result, even though these entities may be available to provide health care services, and/or sexual assault exams, they may not be included in the local response plan, or aware of the issues that need to be addressed, e.g. providers available to perform follow up care, etc.

[9] Illinois, Kentucky, Maryland, Massachusetts, New Jersey, North Carolina, Texas.



Payments for sexual assault exams and all other health care services should be available to sexual assault victims that receive a sexual assault forensic exam

Under the current system, the state, through the Sexual Assault Forensic Exam (SAFE) program, covers all costs directly associated with a sexual assault forensic exam. However, for patients to qualify, the exam has to occur within 120 hours of the assault, the assault must occur in Virginia, and a PERK must be included. Patients have a choice about whether to file a police report and can submit the PERK anonymously. Patients are not responsible for the cost to store an anonymous PERK. In addition, patients do not have to pay for follow-up exams *if* they are directly related to the initial exam.

On the other hand, a patient is responsible for all costs if the exam is performed after 120 hours of the assault or the exam does not include a PERK (both *may* be eligible for SAFE program reimbursements but only if the assault is reported to the police and authorized by a Commonwealth's Attorney). A patient is also responsible for any medical costs associated with the assault that are not part of the sexual assault forensic exam, e.g. treatment of injuries that occurred as a result of the assault (e.g. a broken arm), treatment of existing medical conditions, even if they are made worse by the assault, and any follow-up appointments, medications, and/or lab work not directly related to the initial forensic exam. Finally, a patient also is financially responsible for mental health counseling and any medications filled after a sexual assault forensic exam. A patient with medical or mental health costs not covered by the SAFE program can file claims for reimbursement with the Virginia Victim Fund (VVF) administered by the Workers Compensation Commission (WCC). However, in order to submit claims to VVF the patient must file a report to the police and cooperate with the investigation.

JCHC analysis of SAFE payment data, and data provided by the Department of Consolidated Labs where the anonymous PERKs are stored, found that 39% of all sexual assault forensic exams are done anonymously each year. As a result, patients that do not file a police report but obtain a sexual assault

forensic exam cannot submit any of their health or mental health care claims to VVF for reimbursement and the patient is responsible for medical bills not covered by the SAFE program. Of the 968 unique patient claims paid by the SAFE program (2018), only 77 (8%) of the patients filed a claim for reimbursement with VVF.

Billing Third Parties and Dependent Coverage – Explanation of Benefit (EOB) laws need to be updated

HIPAA provides patients with a right to *request* restrictions on protected health information for treatment, payment, or use and disclosure.[10] However, the law is less clear on whether providers and health plans have to accommodate a request and the law provides them with the authority to deny a request. HIPAA law allows states to be more restrictive than federal law in order to protect patient privacy of health information. Some states require carriers to accept patient requests and provide health care providers and patients with a standard form that patients can complete at the time health care services are sought.[11] Virginia's EOB law currently does not protect patients who are adult dependents, victims of sexual assault or domestic/intimate partner violence. Adult dependents include children through age 26, a spouse, or a partner. Victims of sexual assault or domestic/intimate partner violence often do not want anyone, let alone the perpetrator who may be the owner of the health insurance policy, to know that they received health care services after an assault. To protect their privacy many dependents (including college students) may refuse exams and other health care services or may only request prevention services (e.g., to prevent sexually transmitted diseases, unwanted pregnancy, etc.).

Current SAFE program reimbursements do not cover actual costs

JCHC staff found that a majority of hospital administrators did not appear to support forensic nurse examiner programs because of the high cost to operate the programs, low patient volume, and inadequate reimbursements that do not cover the costs. The current rates have not been increased since 2010 when they were established and do not include reimbursement for the time a forensic nurse spends preparing for, and appearing in, court when subpoenaed during a trial. Increasing the reimbursements to cover *all* of the *actual* costs involved in the program may encourage hospitals and other health care providers to operate forensic nurse examination programs and to provide the necessary follow-up care for patients.

[10] 45 CFR § 164.522

[11] California, Massachusetts and Maryland updated their EOB laws to further protect patient privacy.

Current SAFE Program Reimbursement Rates	
Description of Current Program	SAFE Payment
Acute medical forensic exam – within first 120 hours with PERK	$1,200
Non-Acute medical forensic exam – after 120 hours, authorized by Commonwealth Attorney	$800
Follow-up forensic exam	$300
Transportation covered for travel to the initial forensic exam (but not any follow-up appointments), medications for STI, unwanted pregnancy and HIV post prevention covered at time of exam	Memo. of Agreement with providers / vouchers

Increase Reimbursement to Estimated Actual Cost	
Description of Current Program	Recommended Payment
Acute medical forensic exam – within first 120 hours with PERK	$2,823
Non-Acute medical forensic exam – after 120 hours, authorized by Commonwealth Attorney	$1,560
Follow-up forensic exam	$1,046
HIV Follow-up forensic exam (if necessary)	$913
Court Requirements if Subpoenaed	$1,641
Source: JCHC analysis of data provided by INOVA Ewing Forensic Assessment and Consultation Teams (FACT); Bureau of Labor Statistics compensation reports, American College of ER Physicians fact sheet and MarketRealist.com hospital data.	

The Workers Compensation Commission approved the SAFE administrators to pursue rate increases with the Department of Planning and Budget on August 27, 2019. The proposed new rates are:

- Acute medical forensic exam – within first 120 hours with PERK: $2,900
- Non-Acute medical forensic exam – after 120 hours, authorized by Commonwealth Attorney, non-acute (no PERK): $1,800
- Follow-up forensic exam: $1,500

The estimated fiscal impact of these changes is $6 million. The SAFE program administrators also are reviewing a proposal to provide payments for injuries that occur during an assault and five trauma-informed counseling sessions consistent with VVF mental health treatment guidelines.[12] A third option to increase rates may be to increase the current SAFE program rates by inflation. However, neither the SAFE program administrator's proposal nor an inflation adjustment applied to the current rates would cover the costs associated with court appearances as a result of subpoenas.

[12] Counseling expenses must be reasonable and appropriate, crime-centered, time-limited, and for Trauma- and Stressor-Related Disorders. (http://www.cicf.state.va.us/content/mental-health-treatment-request)

An implementation work group should be created to modernize forensic nurse exam claims processing and to determine the feasibility of moving the SAFE program to DMAS

The SAFE program is administered by the Virginia Victims Fund (VVF) as part of the Workers Compensation Commission (WCC). SAFE program reimbursement claims are not processed like traditional health care claims and reimbursement rates are not set by rule or publicly posted. Filing claims to the SAFE program is labor intensive and cumbersome (e.g. fax, mail and email) and the majority of FNE nurses do not understand follow-up care reimbursement procedures. FNE nurses train each other on how to bill the SAFE program, and other health care providers may not be aware that they can be reimbursed for providing follow-up care for patients.

SAFE program claims and other medical expenses incurred by patients should be patient and provider friendly and use standard health care claims procedures for reimbursements. For example, claims should be filed electronically, a modifier designating the claim as a forensic nurse examine should be created in order to appropriately bill, suppress EOBs and coordinate benefits among the different state funds and other sources of reimbursements that may be available to patients. There should be comprehensive provider training to insure that all health care providers are aware of the process and procedures related to reimbursements for follow-up care. An implementation work group could examine all of these issues and make recommendations to improve claims processing and determine if moving the SAFE program to DMAS is feasible. DMAS has all of the systems necessary to improve SAFE payment program claims processing and procedures.

Policy Options and Public Comments

The JCHC received six comments:

- Kristi S. Wright, Director of Legislative and Public Relations, **Office of the Executive Secretary, Supreme Court of Virginia (SCV)**
- Barbara Allison-Bryan, MD, Chief Deputy for the Department of Health Professionals, on behalf of the **Board of Nursing (BoN)**
- Rebecca Simmons, Executive Director of **Valley Children's Advocacy Center (VCAC)**
- April Rasmussen MSN, SANE-A, SANE-P, Forensic Nurse Examiner, Coordinator, **Centra Health (CH)**
- Michael C. Maslow, Assistant Chief of Police, Investigative Services Bureau, **Norfolk Police Department (NPD)**
- Bill and Amy O'Keefe

Policy Option	Description	Support	Oppose
1	Take No Action		
2	a. Introduce legislation to amend the Code of Virginia to create a subcategory of forensic nurse examiner in nursing law. b. Introduce a budget amendment, language only, requiring the Board of Nursing to create a forensic nurse examination training task force to standardize the training requirements for forensic nursing. Standards should	Rebecca Simmons Bill and Amy O'Keefe	BoN

Policy Option	Description	Support	Oppose
	include grandfathering of existing forensic nurses and those in training at the time of standards adoption. The task force appointments shall include forensic nurse examiners, hospital administrators, a representative from the State Council of Higher Education for Virginia (SCHEV), and other relevant stakeholders as deemed appropriate by the Board. c. Introduce a budget amendment, language only, requiring the State Council of Higher Education for Virginia (SCHEV), in coordination with the task force created by subsection b. of this policy option, to create criteria and requirements necessary for a nursing school to qualify as an officially recognized FNE school and to create and maintain a list of approved didactic training and clinical training locations where forensic nurse education and training can be obtained to meet the Virginia forensic nurse examination training standards.		
3 **6-6** **FAILED**	Introduce legislation to amend the Code of Virginia to require all hospitals to have a forensic nurse examiner *protocol* that includes maintaining a referral call list and identifying hospitals with forensic nursing services with an indicator on license renewal applications, and to train hospital employees on the protocol. Recommended language: ____. Shall require that each hospital establish patient-centered trauma informed protocols for the screening, admissions, treatment, *or* the appropriate transfer of patients seeking any type of forensic examination related to sexual assault, domestic/intimate partner violence, human trafficking, or adult or child abuse, to a hospital where such services are provided and available at the time of referral; that all employees of emergency departments receive training appropriate to the needs of the patient and that such training be based on a trauma-informed approach in identifying and safely addressing situations involving the safety and privacy of the patient and their needs; that, as part of the protocol, each hospital provide to each person requesting or presenting or whose screening indicates a sexual assault forensic examination an information sheet for sexual assault patients that includes information on (i) informed consent, (ii) a description of the medical forensic examination, including costs and reimbursements for medical forensic examinations, (iii) an explanation of the choice to report to law enforcement and examination options, (iv) the risks of contracting a sexually transmitted infection, (v) pregnancy	Rebecca Simmons Bill and Amy O'Keefe	

Policy Option	Description	Support	Oppose
	risks, (vi) information about the Virginia Victim Fund, including a contact information and email address, and (vii) information about advocacy support, including contact information and email addresses to advocacy centers.		
4  7-6 Amended	Introduce legislation to amend § 15.2-1627.4 of the Code of Virginia by adding the following. In addition, the attorney for the Commonwealth shall invite other individuals, or their designees, including: local health department district directors; hospital administrators from each licensed hospital within the jurisdiction; safety-net provider clinic directors from each clinic within the jurisdiction (including those created by 42 CFR 491.1 and the free and charitable clinics); and any other local health care providers to participate in the annual meeting. Attendance shall be encouraged but is not required. Attorneys for the Commonwealth are authorized to conduct the sexual assault response team annual meetings using other methods to encourage attendance, including conference telephone calls and videoconferencing as provided by Title 2.2 (§ 2.2-3708.2) Chapter 37.	Rebecca Simmons Bill and Amy O'Keefe	
5  13-0	Introduce legislation to amend the Code of Virginia to allow victims of sexual assault to access victim funds for all medical expenses regardless of whether a victim chooses to report a sexual assault to law enforcement or chooses to have an exam without a PERK.	Rebecca Simmons Bill and Amy O'Keefe	
6  13-0	Introduce legislation to amend the Code of Virginia to require the Bureau of Insurance to establish regulations, and the Department of Medical Assistance Services to require in its contracts with managed care companies, that covered individuals and members receiving health services can choose a preferred method of receiving the explanation of benefits form from their insurer as permitted by 45 CFR § 164.522; restrict information contained in the EOB if it contains a description of sensitive services. Authorize the Bureau of Insurance--in consultation with experts on infectious disease, reproductive and sexual health, domestic violence and sexual assault, mental health, and substance use disorders--to define sensitive health care services.	Bill and Amy O'Keefe	
7	Introduce a budget amendment requiring the SAFE program administrator to increase reimbursement rates for sexual assault examinations to the actual costs of the exams and to include reimbursements for the costs associated with preparing for, and appearing in, court	Bill and Amy O'Keefe	

Policy Option	Description	Support	Oppose
	when a forensic nurse is subpoenaed during a trial. The actual costs, as calculated by JCHC are estimated to be: Acute medical forensic exam – within first 120 hours with PERK, $2,823; Non-Acute medical forensic exam – after 120 hours, authorized by Commonwealth Attorney, $1,560; Follow-up forensic exam, $1,046; HIV Follow-up forensic exam (if necessary), $913; Court Requirements if Subpoenaed, $1,641. (Alternative options: increase SAFE program rates by (a) the SAFE program administrator's proposal, or (b) by a healthcare inflation adjustment. However, please note that the these alternatives do not include costs associated with any of the court requirements as a result of subpoenas.)		
8  **13-0 Amended**	Introduce a budget amendment, amount to be determined, if any, creating an Implementation Work Group (IWG) led by the Office of the Secretary of Health and Human Resources to determine the feasibility of transferring the SAFE program and all related claims for medical expenses related to sexual assault, strangulation, domestic/intimate partner violence, human trafficking, and adult or child abuse from the Virginia Workers Compensation Board to the Department of Medical Assistance Services. The Implementation Work Group should also include members from the Office of the Attorney General, the Office of the Secretary of Public Safety and Homeland Security, the Office of the Executive Secretary of the Supreme Court, the Workers Compensation Commission, Department of Medical Assistance Services, Department of Criminal Justice Services, and Department of Planning and Budget. The IWG shall make a recommendation regarding whether to increase reimbursement rates for sexual assault examinations to the actual costs of the exams and to include reimbursements for the costs associated with preparing for, and appearing in, court when a forensic nurse is subpoenaed during a trial. If not feasible to move to DMAS, the work group shall create an efficient, seamless electronic medical claim processing system for hospitals and health care providers that coordinates payments from all fund sources, suppresses EOBs and removes patient from the medical billing and reimbursement process. The Implementation Work Group shall present a report with any necessary statutory changes and budget requirements to the Governor, the Chairman of the House Appropriations Committee, the Senate Finance Committee,	Rebecca Simmons Bill and Amy O'Keefe	

Policy Option	Description	Support	Oppose
	and to the Joint Commission on Health Care by September 1, 2020, for consideration in the Executive Budget for SFY-2021.		

Summary of Public Comments

Kristi S. Wright, Director of Legislative and Public Relations, **Office of the Executive Secretary (OES), Supreme Court of Virginia**, wrote that OES was not notified of recommendations in the presentation. OES Takes no position on the transfer of the SAFE program, does not see a role for OES on an implementation task force, and informed JCHC that fund transfers to the Victim Fund are determined by the General Assembly not OES.

Barbara Allison-Bryan, MD, Chief Deputy for **Department of Health Professionals and the Board of Nursing**, wrote that a separate license for forensic nursing is not required. The general nursing license allows for practice in many specialty settings, including forensic nursing. Nursing employers regularly determine a registered nurse's suitability and qualifications for a particular role. Increased regulation of forensic nurses would place an additional financial burden on these nurses and would create a barrier to practice in this role. In addition, the Commonwealth seeks less regulation, not more and the department is not aware that the International Association of Forensic Nurses is petitioning for this sort of legislation as nationally accepted educational guidelines already exist.

Rebecca Simmons, Executive Director of **Valley Children's Advocacy Center**, agrees completely and whole-heartedly with recommendations (policy options) 2, 3, 4, 5 and 8. Expressed uncertainty about recommendation 6 and its implications, as well as recommendation number 7. While it seems increased payment of exams would help smaller localities potentially offer better services, there may be unintended consequences to raising that payment too much and/or too quickly.

April Rasmussen MSN, SANE-A, SANE-P, Forensic Nurse Examiner, Coordinator, **Centra Health**, asked for clarification on the maps and information on services provided around Lynchburg. She also notified JCHC that Gretna ER has forensic nurses on site, there is a Children's Advocacy Center in Forest with Forensic nurses on site and Centra plans to expand forensic services to Bedford and to Southside hospitals in the next year or so.

Michael C. Maslow, Assistant Chief of Police, Investigative Services Bureau, **Norfolk Police Department**, stated that the Norfolk Police Department's Special Crimes Unit utilizes Chesapeake Forensics to conduct SANE exams and collect PERKs. Chesapeake Forensics is a locally based organization and his department does not experience delays in receiving SANE exams for victims of sexual assault.

Bill and Amy O'Keefe wrote that they have been following forensic nursing issues for over a year and they endorse all 7 Recommendations (policy options). The O'Keefe's state that it is important for appropriate training concerning the complex nature of abuse trauma be extended to the criminal justice system, law enforcement officers, prosecutors, and judges. The O'Keefe's believe that all hospitals should have a program for forensic training and treatment; and that rural hospitals, at a minimum, can adopt a protocol for conducting forensic exams and how to initially deal with victims. The O'Keefe's recommend that fully staffed and equipped Centers of Excellence be established throughout the

Commonwealth that can be linked to those hospitals that cannot afford comprehensive, full time programs; the Centers of Excellence can provide training and advice for dealing with victims, and have the capability to dispatch a forensic nurse on an as-needed basis. They indicate that the Bon Secours program could serve as a model for developing the Center of Excellence concept. The O'Keefe's also recommend that privacy concerns be addressed. They suggest the director of forensic nursing at Bon Secours and a representative of the Virginia Board of Social Work be added to the Forensic Nurse Examination Standards Task Force.

Supported Decision Making for Individuals with Intellectual and Developmental Disabilities

Stephen Weiss, MPA,
Senior Health Policy Analyst

Study Information

House Joint Resolution 729 (Delegate Kory) requested the Secretary of Health and Human Resources study supported decision-making (SDM) for individuals with intellectual and developmental disabilities (IDD). The study was approved by JCHC members at the May 8, 2019, work plan meeting. The study topics include the uses of SDM, policies and practices used in other states, whether SDM can be an appropriate alternative to guardianship, stakeholder opinions, recommended strategies to insure that individuals with intellectual and developmental disabilities are informed of SDM, and whether legislation is necessary, and if so, legislative recommendations.

Previous Study and Other Activity Related to SDM in Virginia

SDM was studied in 2015 by the Secretary of Health and Human Resources and a report, House Document 6, was issued to the Governor and General Assembly. The report indicated that Virginia had no official position on SDM with no defined policies or practices and secommended the following: that SDM be added to the guardianship and DBHDS authorized representatives code sections, require SDM and Person Centered Planning training for guardians and authorized representatives, and standardize procedures for capacity evaluations that determine the need for guardianship. No actions were taken by the General Assembly following the report.

As a result of a 2012 code change requiring person-centered practice procedures for public guardians,the Department of Aging and Rehabilitation Services (DARS) implemented an inclusive decision-making process by rule in 2016 that was focused on the expressed preferences, personal values, and needs of the individual with the goal of empowering and supporting individual decision-making as much as possible.[13] Prior to this , Prior to this, in 1997, the private guardianship code was amended to encourage participation in decisions and consider the expressed desires and personal values of a person by guardians.

What is SDM for individuals with IDD?

SDM is based on the understanding that everyone needs help making decisions at times and persons with IDD differ only in degree and/or frequency of assistance needed. SDM helps a person identify where they may need assistance and can be a valid contract that is recognized by law, voluntarily entered into between one IDD adult and at least one supporter. It may be used in lieu of, or in combination with, a guardianship. Under SDM the supporter is not the decision-maker.[14] SDM can be

[13] VA Code § 51.5-150 and 22VAC30-70-30.F

[14] SDM can also be an informal agreement between the IDD and others but does not provide the legal protections that a contract can provide.

used to preserve individual rights that are often lost due to the current guardianship process. SDM, when legally recognized in Code, may be the least restrictive alternative for a disabled person that can be used to both provide a person with the dignity to assume risk and to provide legal protections against abuse.

Delaware, Indiana, and Texas SDM laws are profiled in the JCHC study. All three states consider SDM as a less restrictive substitute to guardianship for disabled adults. These states recognize SDM as a way of supporting and accommodating an adult in the decision making process without impeding self-determination. The states provide guidance in establishing agreements and contracts between the IDD individual and the person(s) he/she chooses to provide decision-making assistance when needed. Supporters are usually family members or friends that the IDD individual trusts and can contact to provide recommendations on matters such as legal, financial, health care, employment, and housing issues.

What is Adult Guardianship?

Adult Guardianship is a judicial determination that concludes that an adult person lacks the capacity to make decisions for him or herself. A person under guardianship loses a variety of decision making rights that may include: the right to vote, make medical decisions, bank and make financial decisions, the ability to file lawsuits in their own name, sign a power of attorney and an advanced directive, choose where to live, work, drive a car, own a gun, etc.[15]

Virginia guardianship can be private or public, limited or full. The process is the same regardless of the type of guardianship. A person petitions the ciruit court of jurisdiction where the person of concern lives. The ciruit court judge appoints a guardian ad litem to review the petition and follow an extensive process to determine if the person of concern needs a guardian and what decision-making rights might be removed or retained based on the person's demonstrated level of capacity. A hearing is held where the circuit court judge considers a report from the guardian ad litem as well as information presented at the hearing. Guardianship may be approved if the judge finds that the person lacks decision-making capacity. The judge also may determine what decision-making rights a person may lose and retain. When a person retains decision-making rights the guardianship may be considered a "limited guardianship". Each guardianship case is different and the final determinations are tailored to the needs of the person of concern. People who are indigent and/or have no other proper and suitable person willing and able to serve as a guardian, may be appointed a public guardian through the public guardianship program operated by DARS. Otherwise the judge will appoint a private guardian who may be a family member, friend, or other interested person. All guardians, regardless of type, are required by law to file annual reports to local department(s) of social service. The reports are then submitted to the Circuit Court Clerk.[16]

[15] Article II, Section 1 of the Constitution of Virginia, VA Code § 64.2-1601 et. seq., and VA Code § 54.1-2981 et. seq.

[16] Private guardianship, VA Code § 64.2-2000 et. seq.; Public guardianship, VA Code § 51.5-149 et. seq.; Limited guardianship, VA Code § 64.2-2009

Public guardianship compared to private guardianship

The public guardianship program administered by DARS operates in collaboration with the Department of Behavioral Health and Developmental Services (DBHDS). The program is regulated and publicly funded. Public guardians are required to have face-to-face visits at least once a month with their ward, provide an annual review to determine if guardianship remains appropriate, utilize person-centered planning, maintain client files that are subject to audit, and attend trainings. The public guardianship program limits the staff-to-client ratio to 1-to-20. According to DARS, 13 organizations serve as public guardian through contracts with the state. [17] There are approximately 12,000 private guardians and 1,049 state funded public guardians in Virginia. [18]

Private guardians, on the other hand, are not regulated. Private guardians are required to file annual reports with the local department(s) of social services. The local department(s) of social services turn the annual reports over to the circuit court clerk.

DBHDS - "authorized representatives"

In addition to the guardianship process outlined in code, DBHDS uses "authorized representatives" in lieu of guardianship. A determination of capacity is made by the director of a local DBHDS or CSB program based on an evaluation of the person of concern by a licensed professional. If the program director determines that a person in treatment is not capable of making health and mental health care decisions for themselves the director will appoint a substitute decision maker, usually a family member. However, The authorized representative does not automatically transfer when a person moves to an area served by a different program or CSB and, Under the DBHDS rules, capacity determinations are reviewed regularly.[19]

Findings

Authorized representative designations should be reported to the state

Authorized representatives are appointed by local mental health program directors after a person is formerly evaluated by an independent "licensed professional" and determined to lack decision-making capacity "to consent to treatment, services, or research or {when the ability} to authorize the disclosure of information is in doubt."[20] Currently, DBHDS is able to identify IDD clients who have guardians, conservators and/or powers of attorneys. [21] The Department, however, does not collect data to determine how many individuals served by the mental health system have a "program-director-appointed" authorized representative, what decision-making rights the person has lost, or how long those appointments are in effect. The Department should report data on the number of authorized

[17] 22VAC30-70-10 et. seq.

[18] The estimated number of private guardians is based on the number of annual reports filed with local departments of social services. DARS reports that of the 1,049 public guardians, 454 slots are reserved for the ID/DD referred by Community Service Boards, 98 are reserved for individuals coming out of state mental health inpatient facilities, and 497 are unrestricted, generally individuals with dementia or a traumatic brain injury.

[19] VA Code § 37.2-400 et. seq. and 12VAC35-115-146 et. seq.; The need for authorized representatives is reviewed every 6 months, upon the request by the person in treatment, at discharge; and annually by the program if still in effect.

[20] 12VAC35-115-146

[21] 8,800 of the 27,000 DBHDS clients who are either enrolled (~14,000) or on the wait list (~13,000) for IDD Medicaid Waiver services have a guardian, conservator or powers of attorney.

representatives appointed in the mental health system so that the data can be included in information on how many people in the state are formally considered to lack decision-making capacity.

SDM should be legally recognized in Virginia for the IDD and Guardians Ad Litem should consider SDM as a viable option in their report to the circuit court

Adding SDM to the VA Code makes clear to the courts and others that SDM is a viable alternative to guardianship and will provide a legal framework for IDD individuals that physicians, hospitals, banks, landlords and others can rely on when doing business with those who have entered into an SDM contract. Once added to the code, guardians' ad litem should review SDM as an option or alternative to guardianship. The guardian ad litem report should include information to the court on whether a person may benefit from SDM in lieu of a guardian. Recognizing SDM by law does not change current guardianship laws or remove the ability of a person to petition the circuit court for guardianship.

Annual Report and Circuit Court data additions can improve reporting and evaluating guardianship determinations

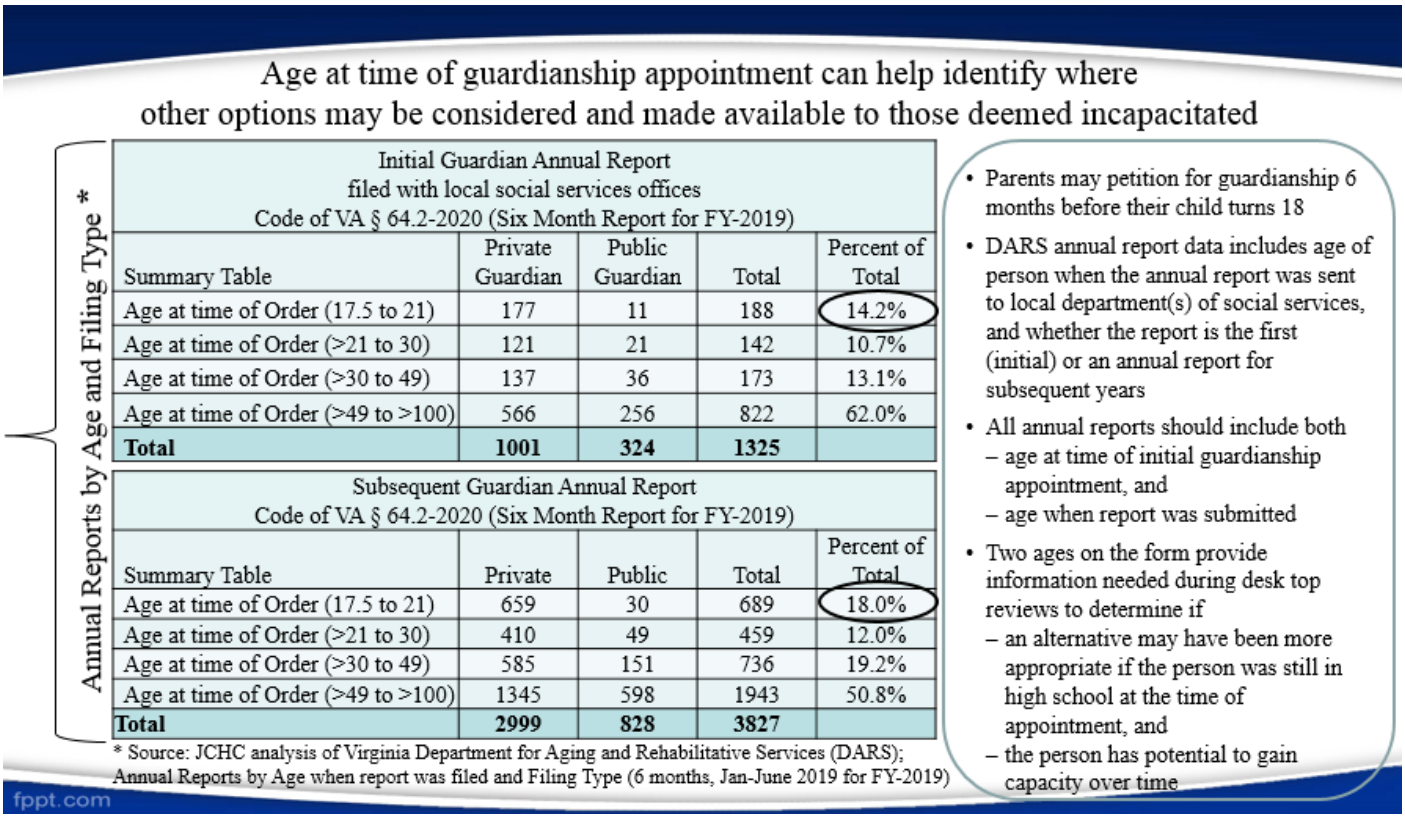
Annual reports are submitted by guardians to local department(s) of social services and then submitted to the court clerks where the guardianship orders originate. The annual report form is prepared by the Office of the Executive Secretary of the Supreme Court (OES). Virginia code lists seven items that are covered on the form.[22] However, the annual report form does not include the age of the incapacitated person at time of initial guardianship appointment, what type of guardianship was ordered (limited, temporary or full), the reason for guardianship (IDD, dementia, mental illness), the relationship to person or profession of the guardian.

In addition, OES maintains the Circuit Case Management System (CCMS). Of the 120 circuit courts, only Fairfax and Alexandria do not report data to the CCMS. The code permits OES to aggregate the circuit court data for statewide reporting purposes.[23] CCMS fields currently do not include date of birth or age at time of initial guardianship appointment or the reason for the guardian appointment.

Adding items to the annual report and to the CCMS will improve data collection and reporting. In addition, if the annual reports and CCMS data fields include age and reason for determination they can be reviewed periodically to determine if there is a change in capacity that may influence a change of the guardianship order.

[22] VA Code § 64.2-2020 - medical and mental health condition; living arrangements; services provided to meet needs; visits by guardian; guardian statement on agreement with treatment and habilitation plan; need for continued guardianship with possible proposed changes; whether the guardian incurred expenses; requests for reimbursement and from whom; and amount of compensation.

[23] VA Code § 17.1-502 and VA Code § 17.1-208.



Virginia Department of Education (DOE) should update special education transition materials for students and parents; and Guardians Ad Litem should consider Individualized Education Program (IEP) when preparing reports for those between 17.5 through 21 years of age

People find out about guardianship in a variety of ways. For parents with IDD children one way is through the school system. During the JCHC study, many of those interviewed indicated that parents with IDD children often pursue guardianship based on a suggestion from someone at the child's school. A small anonymous survey through VCU's Partnership for People with Disabilities found that 9 of 28 (32%) respondents were told to pursue guardianship by school personnel. A 2015 national study of parents and the disabled found that 20% of the responses to a survey indicated that guardianship was "suggested" by school personnel.[24]

A child with a developmental disability who is in school and found eligible for special education services will have an "Individualized Education Program" (IEP; 20 U.S. Code § 1400, et. seq.). The IEP is updated annually and includes individual goals, progress, and age appropriate transition from school to post graduation that may begin when the child turns 14, or when entering post-secondary school. The IEP transition plan developed when the child turns 16 must include information about services that can be put into place when the child is 18 years old. Finally, one year before the child turns 18, students/parents are informed of education rights that are transferred to the student when the child

[24] JCHC analysis of Table 1. Q.5. Jameson, J. Matt., et. al. Guardianship and the Potential of Supported Decision-Making with Individuals with Disabilities. Research and Practice for Persons with Severe Disabilities. June 29, 2015.

reaches the age of 18. Parents are encouraged to get a Power of Attorney for Educational. The VDOE material provided to school divisions and parents mentions guardianship but does not explain what happens when a guardian is appointed, e.g. loss of rights. In addition, some of the material is dated and needs to be updated.

Guardians Ad Litem play a pivotal role in guardianship proceedings. The review and report by guardians' ad litem for those aged 17 through 21 should include a review and report on the person's IEP if the disabled student was in special education. This will provide the judge with information on how well the person learned and advanced in school and whether or not the person has the opportunity or ability to gain a certain level of decision-making capacity over time. Guardianship appointments may be better tailored to the young person's actual needs, e.g. limited or temporary, retention of certain decision-making rights, etc.

Virginia's Guardianship Code can be difficult to follow and should be updated and clarified

Parents, family members and others may seek information about guardianship directly from the VA Code. The code should be "user" friendly. Definitions should be added, cross references to other sections of code should be linked directly to the references, and sections providing information on what the responsibilities of a guardian are should be clarified.

Judicial orders for guardians should include standard language to provide clear guidance to guardians and others

The guardianship order is the document used by all guardians as the legal guide in working with a person. Guardianship orders are written by petitioning attorneys. A JCHC staff review of different orders found that some lacked basic information, such as: whether the order was a full or limited guardianship, what rights a person retained and lost, requirements to file annual reports, basic responsibilities of guardians, and that guardianship can be changed or reversed.

Policy Options and Public Comments

The JCHC received six comments:

- Kristi S. Wright, Director of Legislative and Public Relations, **Office of the Executive Secretary, Supreme Court of Virginia (OES)**
- Colleen Miller, Executive Director, **disAbility Law Center of Virginia (dALCV)**
- Lucy Beadnell, Chair of the **Virginia Ability Alliance (VAA)** and Executive Director of the **Arc of Northern Virginia (ArcNOVA)**
  - 33 letters of support for the Virginia Ability Alliance's comments were submitted: 26 from individuals and 7 from representatives of organizations

Policy Options

Policy Option	Description	Support	Oppose
1	Take no action.		VAA – strongly oppose
2	Introduce legislation to amend VA Code § 37.2-401 by adding a subsection B. to improve data collection and reporting on all persons in Virginia who are determined to be incapacitated, require DBHDS to record information concerning whether a consumer of mental health system services has an authorized representative.	VAA	
3  **10-1**	Introduce legislation to add a new section to the VA Code, Title 37.2 (Behavioral Health and Developmental Services) and/or Title 59.1 (Trade and Commerce) creating SDM for Individuals with Developmental Disabilities and/or all disabled adults as an option for DBHDS and to formalize a supported decision making contract in code that provides protections for private individuals that want to use a contract (e.g. use Delaware law as model: 80 Del. Laws, c. 427; Code § 9401A, et. seq.).	VAA	
4  **12-0**	Introduce legislation to amend VA Code § 64.2-2003.C. by adding a requirement that guardian ad litems consider whether supported decision making is a viable option when reviewing and reporting on the extent of the duties and powers of the guardian or conservator.	VAA – strongly	
5	Introduce legislation to amend VA Code § 64.2-2020 to increase the list of questions on the annual report form prepared by OES to include age of incapacitated person at time of appointment, what type of guardianship was appointed (full, limited, temporary), reason for appointment (e.g. IDD, dementia, mental illness), and guardian's relationship to the incapacitated person.	VAA	
6	Introduce legislation to amend VA Code by adding a new subsection to require each circuit court to add fields in their case management system to identify date of birth or age at time of a guardianship appointment and reason for appointment (e.g. IDD, dementia, mental illness).	VAA	

Policy Option	Description	Support	Oppose
7 AMENDED  **12-0**	Introduce ~~a Section 1 bill~~ legislation directing VDOE to update special education transition materials for students and parents; directing school divisions to use the VDOE material to the fullest extent possible and include more information about transition for students and parents during the annual IEP meetings related to health care and other options available, including supported decision making.	VAA – strongly	
8  **8-3**	Introduce legislation to amend VA Code § 64.2-2003 to include a requirement that a person's IEP be part of the GAL's review and report for those between 17.5 through 21 years of age.	VAA	
9  **12-0**	Introduce legislation to amend VA Code § 64.2-2000, et. seq. to clarify the code sections as follows: § 64.2-2000, definitions should be more complete so prospective guardians, family members and others are aware of what is included in the Code. Definitions should be added for: ∗annual reports required by § 64.2-2020 (to indicate oversight) ∗guardian ad litem required by § 64.2-2003 (to clearly identify who will review and report to the judge at the hearing) ∗temporary guardian and conservator (clearly defined options to pursue, ask questions about) ∗power of attorney(s) to inform (clearly defined options to pursue, ask questions about) ∗Individual Education Plan (20 U.S. Code § 1414) that should be reviewed by guardian ad litem for persons between the ages of 17.5 through 21 Code clarifications: ∗the advanced directive reference in the definition section currently refers to the short title of the health care decisions act and not to the definition of advanced directive, the reference should be directed to the actual definition in § 54.1-2982 ∗"Guardian" definition should include a reference to the duties and powers section § 64.2-2019 of a guardian	VAA	

Policy Option	Description	Support	Oppose
	∗§ 64.2-2007.C. related on the petition hearing should include a reference to § 64.2-2019.E. to make it clear that, to the extent feasible, the respondent (the subject of the hearing) will be encouraged to participate in decisions, act on his or her own behalf, and to develop or maintain the capacity to manage personal affairs if the respondent retains any decision-making rights		
10  **12-0**	Introduce legislation to amend VA Code § 64.2-2007 by adding a requirement that the following language be included in all guardianship orders: ∗Clearly state whether the order is a full order removing all rights, a limited order and what rights are removed from the respondent {incapacitated person}, and/or a temporary order indicating the time-frame that the order is in effect for. ∗A guardian, to the extent possible, should encourage the incapacitated person to participate in decisions, consider the expressed desires and personal values of the incapacitated person to the extent known, shall not unreasonably restrict an incapacitated person's ability to communicate with, visit, or interact with other persons with whom the incapacitated person has an established relationship pursuant to VA Code § 64.2-2019. E. ∗Annual reports should be filed by the guardian with the local department of social services for the jurisdiction where the incapacitated person then resides pursuant to VA Code § 64.2-2020. ∗Guardianship orders are subject to petition for restoration, modification, or termination pursuant to the provisions VA Code § 64.2-2012.	VAA - strongly	

Summary of Public Comments

Kristi S. Wright, Director of Legislative and Public Relations, **OES, Supreme Court of Virginia**, wrote that OES will change the annual report form to reflect any additional questions added to the code. Ms. Wright noted that the Circuit Court Case Management System (CCMS) was designed to help the courts manage and process cases. All of the information in a guardianship order is not entered into the CCMS. The addition of fields as recommended in policy option 6 "would have a fiscal impact for OES and would likely also have a fiscal impact for the two circuit court clerks running their own case management systems." In addition, consideration should also be given to privacy concerns that may arise if the "reason for appointment" involves an individual's health information. Ms. Wright further noted that the rationale for recommending the inclusion of the information from policy option 6 in the CCMS is unsupported because the determination that guardianship is appropriate is made by the judge, who has the information in the petition. Ms. Wright also noted that policy option 9, recommending that the

Code of Virginia be "user friendly", should be taken with care to avoid creating conflicts with other provisions of the Code or possibly overturning existing case law. Finally, Ms. Wright recommends that language from policy option 10 may be more appropriate in Va. Code § 64.2-2009 (Court order of appointment; limited guardianships and conservatorships.) rather than Va. Code § 64.2-2007.

Colleen Miller, Executive Director, **disAbility Law Center of Virginia**, stated that the disAbility Law Center supports any legislative effort that improves protections for individual's subject to guardianship, that enhances understanding of less restrictive alternatives, and that allow for the legal recognition of SDM. Ms. Miller noted that SDM is a model for supporting people with disabilities to make their own decisions and exercise capacity. Unlike powers of attorney or advance medical directives, which emphasize surrogate decision making, SDM emphasizes decision making as a skill that can be developed with assistance. Ms. Miller states that while policy option 3 provides a legal structure for SDM, and the agreements may receive legal recognition and protection, legal recognition should not be solely through a formal agreement otherwise SDM may become prescriptive. Policy option 5 could provide critical information for evaluating guardianships individually and systemically. Ms. Miller notes that the information requested in the annual report is critical to determining the involvement of the guardian in an individual's life. Ms. Miller suggests adding language requiring guardians to report annually on their efforts to "encourage the incapacitated person to participate in decisions, to act on his own behalf, and to develop or regain the capacity to manage personal affairs". Policy options 9 and 10 would make the accountability mechanisms in the existing law more explicit and address the need for uniformity and clarity in guardianship orders. Ms. Miller notes that guardianship orders govern the individual's rights on a daily basis and how others - who tend to be highly deferential to the guardian -- interact with the individual. Finally, she notes that the guardianship order is the primary document that the guardian and the individual consider in establishing the relationship between the guardian and the ward.

Lucy Beadnell, Chair of the **Virginia Ability Alliance (VAA)** and Executive Director of the **Arc of Northern Virginia** wrote in strong opposition to taking no action. Ms. Beadnell, as Chair and on behalf of VAA, supports taking action on all of the other policy options. She states that SDM is a growing movement that has numerous benefits, including the empowerment of people with disabilities, reduced stress for parents and caregivers, growth of self-determination skills, little to no cost to implement, and is sustainable over time. Adding SDM to the code would be a meaningful alternative to guardianship, or other more restrictive and expensive alternatives. Ms. Beadnell noted that currently available data is limited, there is a lack of information on how or why "we" are permanently taking away the civil rights of 12,000+ Virginians, and that mechanisms currently exist to collect some limited data therefore making the addition of questions and the collection of DBHDS data a "simple" adjustment. Ms. Beadnell wrote that the guardian ad litems core function is to protect the person with a disability and that must include exploring possible alternatives to removing that person's rights. Guardian ad litems, she wrote, must have a true understanding of how SDM can work for people and review those ideas with the petitioners. Ms. Beadnell stated that, "anecdotally and based upon the many phone calls we receive with inquiries about guardianship, many families are told to seek this option by their school system during an IEP or other meeting." She states that, "School staff must understand the options and implications of the range of legal authority options presented to students and parents and should be making sure that SDM is presented as a reasonable and viable option." Ms. Beadnell reports that GALs traditionally look at formal testing and diagnosis from professionals who are ***not*** in daily communication with the student with a disability. On the other hand, IEPs are created by people who know the person with a disability, demonstrate goals and progress of life skills, work toward employment and can offer a

fuller perspective on a person's current and potential abilities. Ms. Beadnell stated that "most often" non-attorney parents seeking guardianship of people with developmental disabilities {look at the Virginia Code for guidance}. Ensuring the code is written in plain language and parents can read, for themselves, in the law what the options and implications are for their various legal authority choices makes the reality of understanding and exploring options like SDM more likely. Finally, "laypeople, let alone the person under guardianship, cannot read orders as currently written to find out if they have any remaining rights and why rights were removed. If a guardian feels there is no alternative but to restrict visitation rights, that decision should be taken with grave seriousness and continued reassessment. We all expect that our personal beliefs and values will guide our life choices and guardians should be primarily guided by those tenants."

George Rathbone, CCBT, PBSF, Licensed Professional Counselor (MD, VA, DC), **Developmental Support Associates, LLC**, wrote in support of Ms. Beadnell's letter and added that as a clinician for over 35 years he has worked with disabled populations in every setting and noted that the vast majority who are considered "incapacitated" still have the ability to make informed decisions about many life issues. Under the current system many citizens are inappropriately denied their rights, may experience significant harm due to reduced quality of life and increased risk of exploitation, neglect, and abuse at the hands of others.

The position of the VAA, as presented by Ms. Beadnell's letter, is endorsed by 24 individuals and 7 representatives of organizations, including:

* James E. Campbell, Jr., Ph.D., SHRM-SCP, **Community Systems, Inc.- Virginia** (https://communitysystems.org/)
* Eva-Elizabeth Chisholm, Human Services Leader, **L'Arche Greater Washington DC** (https://larche-gwdc.org/about-us/)
* Uchenna Egenti, **Disability Rights Advocate**
* Grace L. Francis, Ph.D., Assistant Professor, Special Education, **George Mason University**
* Kathy Adams, Board of Directors, **Parents of Autistic Children of Northern Virginia** (https://poac-nova.org/who/)
* Rachel Payne, Ph.D., Vice President of Advocacy and Public Policy, **Didlake** (https://www.didlake.org/)
* Steven R. Jones, CAE, **Nonprofit Essentials Consulting**

Dispensing of Drugs and Devices Pursuant to Pharmacy Collaborative Practice Agreements, Standing Orders, and Statewide Protocols

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Background

House Joint Resolution 662 (Delegate Stolle, 2019 session) directs the Joint Commission on Health Care (JCHC) to study the current laws and regulations, and roles and responsibilities of pharmacists and other providers, pertaining to prescribing, dispensing and administering drugs and medical devices. The study focus should include pharmacy collaborative practice agreements, standing orders, and statewide protocols; as well as the legal liability of pharmacists and other health care providers who prescribe, dispense, and/or administer medications and devices. Finally, Commission staff should identify changes in Virginia Code or regulations "that would enhance patient access to health care in the Commonwealth."[25]

Pharmacy Workforce and Education

Eighty-one percent of 478 respondents to the Department of Health Professions Workforce Data Center's most recent survey who indicated that they participate in a collaborative practice agreement (CPA) reported that they earned a PharmD degree while 16% reported having earned a Bachelor's degree. The Virginia Commonwealth University (VCU) School of Pharmacy no longer confers Bachelor's degrees; all degrees are doctoral level. This is a national trend.

The Accreditation Council for Pharmacy Education determines key elements for PharmD programs, which includes skills in patient assessment and history takings, drug allergies, identifying risk for prevalent diseases, establishing and follow up of a care plan, minimize risk for adverse drug events and errors, and knowing when a patient needs a referral to a physician. The VCU pharmacy program requirements include 73 credit hours of prerequisites including biology, chemistry, physiology, anatomy, microbiology, biochemistry, genetics and immunology. The pharmacy curriculum includes 155.5 credit hours over 4 years that include in-depth training on all body systems, patient assessments, and ordering and interpreting laboratory tests.

25 House Joint Resolution 662, 2019 Virginia General Assembly Session.

Laws and Regulations

Parties to an Agreement

The *Virginia Administrative Code* Chapter 18. Sections 110 – 70 addresses CPAs. The code defines *practitioners* and *pharmacists* who may be parties to a CPA. Currently, the code references the definition of practitioners that includes nurse practitioners (NP) and physician assistants (PA) who practice under a practice agreement with a medical doctor, doctor of osteopathy or podiatry. It does not reference the code section that defines NPs and PAs that may practice independently without an agreement with a physician, osteopath or podiatrist. Board of Pharmacy staff indicated that this was an oversight. **The JCHC may wish to include the code section that defines independently practicing NPs and PAs, or more broadly, any person that the state allows prescribing authority as a *practitioner* in the CPA regulations.**

Reimbursement for Pharmacist Services

VAC 38.2-3408, which went into effect October 1, 2019 states that:

*"B. If an accident and sickness insurance policy provides reimbursement for a service that may be legally performed by **a licensed pharmacist, reimbursement under the policy shall not be denied** because the service is rendered by the licensed pharmacist provided that (i) the service is performed for an insured for a condition under the terms of a collaborative agreement, as defined in § 54.1-3300, between a pharmacist and the physician with whom the insured is undergoing a course of treatment or (ii) the service is for the administration of vaccines for immunization. Notwithstanding the provisions of §38.2-3407, the **insurer may require the pharmacist, any pharmacy or provider that may employ such pharmacist, or the collaborating physician to enter into a written agreement with the insurer as a condition for reimbursement** for such services. In addition, reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of §38.2-3407.7." (Pharmacies; freedom of choice). C. **This section shall not apply to Medicaid, or any state fund***.

The Department of Medical Assistance Services (DMAS) does not include pharmacists in their definition of *practitioner* due to the fact that pharmacists are not included in the definitions of provider under the Social Security Act regarding Medicare Part B, and under the Family Medical Leave Act. Therefore, DMAS does not have a mechanism in place that would allow pharmacists to bill for services other than drug acquisition cost and dispensing fee. Despite this, DMAS does require that Medicaid Managed Care Organizations (MCOs) reimburse pharmacists for activities provided under Medication Therapy Management programs that is over and above the drug cost and dispensing fee. **The JCHC may wish to introduce a budget amendment to add pharmacists to the list of DMAS providers and amend 38.2-3408 C. to allow pharmacists practicing outside of a CPA to receive reimbursement.**

CPA Protocols

CPAs must include the condition or disease state that the pharmacist will manage and a protocol for that management which is clinically accepted as the standard of care. The parties to an agreement wishing to use a protocol that is not a clinically accepted standard of care must submit the protocol to the Boards of Pharmacy and Medicine for approval. The application fee is $750. Board of Pharmacy (BoP) members indicated that the criteria for which to judge a non-standard protocol is the existence of

evidence published in a peer-reviewed journal that supports the protocol. To date, the Boards have not received any applications for non-standard protocols. In addition, the BoP does not receive copies of CPAs using standard protocols. **Some policy advocates recommend eliminating any requirements for Board approval for CPAs; the JCHC may wish to remove that requirement.**

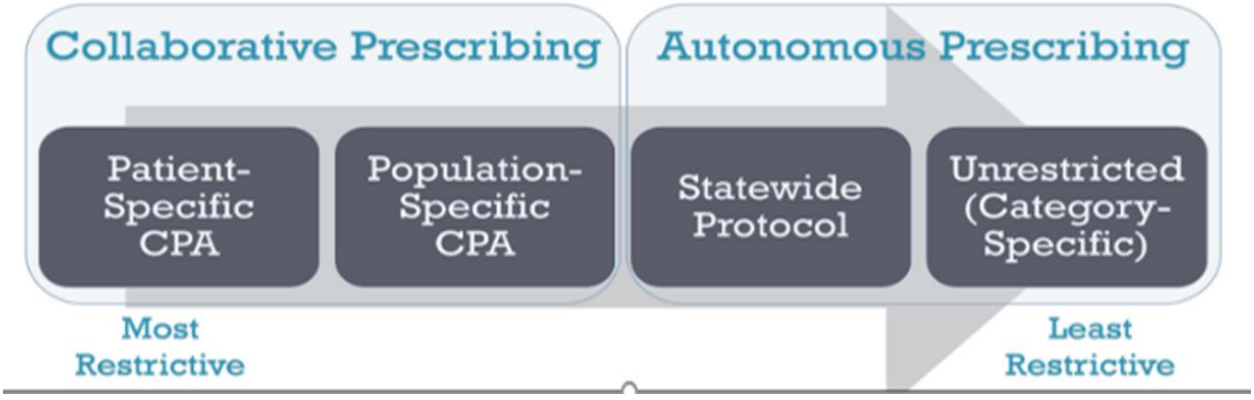
Liability

The Code of Virginia, Title 8.0. Civil Remedies and Procedures Chapter 21.1 Medical Malpractice, defines the term *health care provider* and includes pharmacists in the definition. Section 8.01.581.15 specifies a schedule of the dollar amount of required liability insurance that a health care provider must maintain. The amount increases periodically, and the schedule goes through 2031. None of the individuals consulted for this study (including key stakeholders) indicated that liability was an issue for CPAs and did not feel it was a barrier to CPA participation.

Scope of Pharmacists' Practice

Prescriptive Privileges

The continuum of scope of practice goes from the most restrictive (patient-specific CPAs) to the least restrictive (autonomous prescribing). Virginia's laws fall in the middle of the continuum. Federal programs, including the Indian Health Service and Veterans Administration allow unrestricted authority to clinical pharmacists. Two laws enacted in the last two years, one in Idaho and one in Oregon, have expanded prescriptive authority for pharmacists through statewide protocols. In Idaho, pharmacists can now prescribe and dispense drugs for a long list of conditions, such as cold sores, seasonal influenza, strep throat, uncomplicated UTIs, and diabetic conditions. In Oregon, pharmacists can now prescribe and dispense drugs that appear on a state-authorized formulary, which will continue to grow upon request and approval. Potential items on the formulary include diabetic testing supplies, smoking-cessation aids, epinephrine auto-injectors, albuterol inhalers, rapid strep tests, and spacers for inhalers.[26]



26 https://www.pbahealth.com/is-pharmacist-prescribing-authority-on-the-rise/

Standing Orders and Statewide Protocols

The terms *protocol* and *standing order* almost are almost used interchangeably; both allow someone other than the provider to enter, modify, or stop an order on the provider's behalf. A *standing order* is an order conditioned upon the occurrence of certain clinical events. The important characteristic of a standing order is that all the patients who meet the criteria for the order receive the same treatment. For example, during an outbreak of influenza, unimmunized individuals who present to a pharmacist with flu symptoms may be tested for the flu using a CLIA Waved test, and if they test positive, they could receive an antiviral medication without having to see a physician. Having to see a physician may delay treatment beyond the window of drug efficacy and result in duplicate testing. A common use of standing orders is in public health clinics that treat specific diseases. *Medical protocols* are sets of predetermined criteria that define appropriate interventions and describe situations in which judgments are made relative to a course of action for effective management of common patient problems, such as nurses' standing orders for dispensing medications or staring intravenous fluids for hospital inpatients.

The *Code of Virginia* allows the Commissioner of Health, or their designee, to issue standing orders for naloxone for opioid overdose and for routine vaccines. There may be conditions that could be identified for which the Commissioner could issue a standing order, such as influenza, urinary tract infections, strep throat and others that could enhance public health, increase timely access to services and perhaps reduce unnecessary health care expenditures, such as visits to an emergency department or urgent care center.

Several states allow pharmacists to dispense certain drugs under statewide standing orders, such as prescription tobacco cessation products, hormonal birth control, anti-viral drugs for influenza, antibacterials for strep throat, and drugs for urinary tract infections. **The JCHC may wish to introduce legislation adding to the list of conditions, such as diabetes or high cholesterol that are included in statewide standing orders. Alternatively, or in addition to expanding the conditions and drugs that can be dispensed via standing orders, the JCHC may wish to authorize the formation of a committee of experts to develop recommendations.**

Policy Options and Public Comments

Comments were received from the following organizations.

- Virginia Department of Health (VDH)
- Virginia Commonwealth University School of Pharmacy
- Virginia Pharmacists Association (VPhA)
- National Alliance of State Pharmacy Associations (NASPA)
- National Association of Chain Drug Stores (NACDS)

Option	Supports	Opposes
1. Take No Action		**1** NACDS
2. Introduce legislation, and accompanying budget amendment if needed, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of *provider* and amend VAC 38.2-3408.	**3** NASPA, NACDS, VPhA	
3. Introduce legislation striking the requirement that parties to a CPA must get approval from the Boards of Pharmacy and Medicine for agreements containing non-standard protocols.	**2** NASPA, NACDS	
 **AMENDED 11-0** **4.** ~~Add *independent practice* nurse practitioners and physician assistants to the list of *practitioners* that can be party to a CPA with a pharmacist.~~ Introduce legislation to amend the definition "collaborative agreement" in § 54.1-3300 to read: "Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; (iv) ***any licensed independent physician assistant;*** *or* ~~*(iv)*~~ *(v)* any licensed nurse practitioner working in accordance with the	**1** NASPA	

provisions of § 54.1-2957 ***including a licensed independent nurse practitioner***, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility. **and** Amend § 54.1-3300.1 to read: (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; (iv) ***any licensed independent physician assistant;*** *or ~~(iv)~~ (v)* any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957 ***including a licensed independent nurse practitioner***, involved directly in patient care which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry, ***and licensed independent physician assistants and independent nurse practitioners,*** shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.		
5. Introduce legislation to expand statewide standing orders to include some, or all of the following conditions for which there are CLIA Waived tests, such as Streptococcus, influenza, Urinary Tract Infections, hormonal birth control, smoking cessation aids, and tuberculosis testing.	**3** NASPA, NACDS, VPhA	

6. Introduce legislation to allow pharmacists limited prescriptive authority, (e.g., for smoking cessation drugs, anti-viral drugs, birth control, etc.) and code change at VAC 38.2-3408 to allow for reimbursement for pharmacists who are acting outside of a CPA.	**4** VCU School of Pharmacy, NASPA, NACDS, VPhA	
 **11-0** **7.** By letter from the JCHC Chair, request that the Boards of Pharmacy and Medicine convene a workgroup of expert stakeholders to determine if statewide standing orders can be expanded to other conditions (e.g., those for which there are CLIA Waived tests).	**1** VCU School of Pharmacy	
8. Introduce legislation to amend 18VAC110-40-40 to allow the practitioner to determine *all* protocols and pharmacists' roles without the Boards' approval.	**2** NASPA, NACDS	
9. Introduce a budget amendment to add pharmacists to the list of DMAS providers and amend 38.2-3408 C.		

Public Comments

Virginia Department of Health

VDH has no position on the issue of standing orders and deferred to the Department of Health Professions.

Staff conveyed that standing orders are limited to those for vaccines and naloxone, and for those designated by the Secretary during an emergency.

The issue of health care workers being able to reach out to identified contacts of persons diagnosed with a sexually transmitted disease was discussed, particularly in relation to a contact who refuses to see a physician. The contact must be assessed for allergies and contraindications for drugs that may be prescribed. Currently, only a Health Department physician may reach out to a contact.

Virginia Commonwealth University School of Pharmacy

They recommend expanding the scope of standing orders to include common infectious diseases (urinary tract, influenza, Strep throat, other CLIA waivered conditions), and smoking cessation (Option 6).

Discussed establishing a committee to develop statewide protocols for conditions such as hypertension, diabetes, renal disease, that would not require a CPA (Option 7).

Payment for expanded services is a significant barrier.

Most, if not all, pharmacists working under a CPA are working in clinics; very few, if any, work in a community pharmacy.

National Alliance of State Pharmacy Associations (NASPA)

There are conditions where a diagnosis is not needed, e.g., someone using tobacco products – pharmacists could dispense smoking cessation drugs (Option 6).

Although there is a Statewide Standing Order for Naloxone, if an insurance company requires pre-authorization, the State Health Commissioner is not going to provide information needed by the health plan – pharmacists' prescriptive authority would remove that barrier (Options 5 and 6).

NASPA supports several of the policy options presented to the Commission and encourages Commission members to take action on the following:

Option 2. Introduce legislation, and accompanying budget amendment, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of provider (enactment of legislation will depend on BA approval) (Option.

Option 3. Introduce legislation striking the requirement that parties to a CPA must get approval from Boards of Physicians and Medicine for agreements containing non-standard protocols.

Option 4. Introduce legislation to add independent nurse practitioners and physician assistants as the practitioner (as defined in CPA regulations) in a CPA.

Option 6. Introduce legislation to allow pharmacists limited prescriptive authority, (e.g., for smoking cessation drugs, anti-viral drugs, birth control).

Option 8. Introduce legislation to amend 18VAC110-40-40 to allow the practitioner to determine all protocols and pharmacists' roles without the Boards' approval.

In addition, NASPA encourages Commission members to introduce legislation clarifying that collaborative practice agreements are not patient-specific and that a separate CPA is not needed for each patient.

Virginia Pharmacists Association (VPhA)

Pharmacists are the most accessible healthcare provider and play a large role in reducing the burdens of access, quality and costs. With this in mind, VPhA endorses the following policy options from the Commission's study presented on October 4:

Policy Option 2: Introduce legislation, and accompanying budget amendment, requiring that the Virginia Department of Medical Assistance Services include pharmacists in the definition of provider (enactment legislation will depend on BA approval). An aging population and provider shortfalls contribute to health care access problems. There are several areas of the state where the provider to citizen ratio falls significantly below the recommended level to achieve balance and optimal outcomes. For DMAS to add pharmacist s to the list of DMAS providers would improve access to the most at need population with some of the worst provider to citizen ratio. In DMAS' recognition of pharmacists as providers for billing services, the payments must reflect the effort and time involved in following the patient from the beginning to the end of the encounter. Pharmacists provide effective and efficient care: Research shows that pharmacists patient care services result in significant cost savings. Allowing patients to access care from pharmacists can help DMAS realize cost savings.

Policy Option 5: Introduce legislation to expand statewide standing orders (prefer to refer to this option as statewide protocols) to include all CLIA waivered tests. Statewide standing orders are easy to develop

and modify, and there is precedent with the Naloxone standing order. The Board of Pharmacy also has experience with issuing statewide standing orders. In response to VDH's concern about pharmacists' level of training to assess/differentiate influenza from pneumonia and other conditions, pharmacists already assess and refer patients on many conditions and will continue to do so. A statewide protocol allowing pharmacists to test and treat if positive for influenza and Streptococcus would allow for accurate and timely treatment. Patients who either do not have a primary care provider or cannot visit one during their established office hours would receive care with appropriate follow up. Pharmacists are available 24/7. All licensed pharmacists, whether clinical or retail, meet the required certification needed to implement any protocol, including performing physical assessments. While some may prefer to only give clinical pharmacists authority, clinical pharmacists make up only 6% of the established practice settings. This practice setting alone would not address the challenge of access and improved outcomes.

Policy Option 6: Introduce legislation to allow pharmacists limited prescriptive authority (e.g., for smoking cessation drugs, anti-viral drugs, birth control). Pharmacists are appropriately trained and capable of practicing autonomously—including post-diagnostic prescribing and prescribing for preventive treatments and treatments for conditions that are easily identified. Autonomous pharmacist prescribing is authorized in many states today and pharmacists are thoroughly trained to select and optimize mediation regimens. Cumberland County recently experienced a scabies outbreak. Many clinics and offices refused to see the patients due to contagious circumstances. Cumberland Pharmacy had plenty permethrin, but no ability to dispense it without a provider. If the pharmacy had prescriptive authority, and maybe an emergency prescriptive authority in this instance, it could have prevented many more cases and treated existing ones. In conclusion, pharmacists are highly trained professionals who are capable, like other providers, of exercising appropriate judgment regarding prescribing and treatment. With the decrease in Family Practice providers and the expansion of Medicaid, the underserved population is growing quickly. Adequately prepared pharmacists can help fill this deficit in care. Pharmacists should not be subjected to more burdensome restrictions than other non-physician prescribers. Excessive regulations increase the cost of healthcare by creating inefficiencies and decreasing access to affordable, effective care.

National Association of Chain Drug Stores (NACDS)

Given the national imperative to improve healthcare quality, the entire healthcare continuum must be evaluated to advance, improve, and innovate. A myriad of compelling evidence demonstrates that greater inclusion of pharmacists in direct patient care is scalable and leads to less administrative burden on other providers, increased cost efficiency, more cohesive teams, and most importantly, improved patient outcomes. Community pharmacists, as the most accessible and frequently visited healthcare team member, complement care provided by others through facilitation of convenient access to affordable, high-quality preventive, chronic and acute care. In fact, the role of community pharmacists has evolved rapidly over the last two decades to include immunizations, screenings, health and wellness, treatment for minor illnesses, medication optimization, chronic care management, and more. Such services are often tethered synergistically to others in the healthcare community to improve care coordination.

Given the evolving healthcare needs of Virginians, we urge the Commission to modernize, innovate, and harmonize the Commonwealth's outdated pharmacy care laws and policies by removing unwarranted

and burdensome restrictions placed on pharmacists, which dampen capacity to fully leverage their clinical expertise and thereby deprive patients of necessary advancements in transformational care services and delivery. Our recommendations are set forth in the NACDS Position Matrix. We also included additional supporting documentation/evidence (for full context, please refer to NACDS' October 1st letter that has been incorporated by reference herein). NACDS greatly values the opportunity to provide support for the reformation of pharmacy practice within the Commonwealth, and we appreciate the Commission's consideration of our recommendations on the proposed policy options.

The NACDS submitted a 103-page document including a wide variety of information addressing the issues covered in the study. In summary, the NACDS favors expanding the scope of pharmacy practice and implementing less restrictive rules than are current in Virginia. Please refer to the attachment in your packet for details.

OPTION	**NACDS Position** Support	Strongly supports JCHC's efforts to "ensure that the Commonwealth as a provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so the greatest number of Virginians receive quality care." Central to JCHC's efforts should be the lifting of rigid and unwarranted restrictions on the full practice of pharmacy care – efforts that will profoundly impact the health of Virginians and improve the health of communities across the state; especially in medically underserved rural areas.
6	Support: 1st Preference	Transformational health care reform is sweeping the country. Approximately 34 states already provide pharmacists with prescriptive authority: 3 states authorize autonomous category-specific pharmacist prescribing and 22 states allow pharmacists to prescribe via statewide protocol/standing order. We urge JCHC to support the modernization of the pharmacy scope of practice laws and policies to build a more expansive public health-centric state framework and provide greater capacity to meet the needs of the Commonwealth by deploying effective and efficient healthcare professionals – including pharmacists – across the care continuum. In so doing, reform policies should be broad enough to support new advances in care delivery, care coordination, and pharmacy care and treatment. Thus, we urge JCHC to support Option 6 with the following modifications: • Strike "limited prescriptive authority" and replacing it with "unrestricted, category-specific prescriptive authority." • Add new Option 9: authorizing pharmacists to delivery all recommended vaccines to the corresponding recipients by ACIP. Such reform will reduce the costs of care services and foster innovation within the state.
5	Support: 2nd Preference	As illustrated in the chart below, the conditions of strep, flu, UTI, hormonal contraception, smoking cessation aids, and TB testing should be effectively encompassed in Option 6 above. However, if Policy Option 6 is not adopted, Policy Option 5 is a permissible alternative. Yet, this option would place significantly more administrative burden on the Commonwealth than Option 6 above.

		If Policy Option 5 is adopted, we urge JCHC to support Option 5, replacing "statewide standing orders" with "statewide protocols."
3	Support: 3rd Preference	As stated above, to improve the health of all Virginians, pharmacists should unequivocally have unrestricted, category-specific prescriptive authority (Option 6 above; with Option 5 as a fallback). Such reforms would modernize pharmacy care policies, removing the need for burdensome collaborative practice agreements in the Commonwealth. However, if prescriptive authority is not broadened enough through other policy changes, we strongly support modernizing the existing, highly restrictive collaborative practice policy by concurrently adopting Policy Options 3, 4, and 8. In so doing, we would require the following additional stipulation: allow prescribers to authorize pharmacists to prescribe, modify, discontinue, initiate, etc. medications and therapies.
8	Support: 4th Preference	See Option 3 comment above.
2	Support: 5th Preference	Consistent with research and ongoing programs in the Commonwealth, Option 2 would be extremely beneficial to enhance health equity. See CMMI Carilion Clinic Grant Preliminary Results[27,28] and A&B Pharmacy & Emporia Medical Associates Team-Based Care Program[29,30] aimed at rural, underserved Virginians. NACDS supports Option 2 – a synergistic reform to Option 6 above.
4		See Option 3 comment above.
7	Strongly Oppose	Instead of undertaking on another burdensome administrative effort, JCHC should acknowledge that there is ample evidence and success from other innovative states and federal programs to support an immediate reform approach as outlined in Option 6 above. To this end, we urge JCHC to provide broader access to care and scale successful innovations by authorizing full prescribing and coverage of community pharmacy health care services to the broadest extent for the ultimate and immediate benefit of Virginians.
1	Strongly Oppose	The Commonwealth cannot afford to maintain the status quo given the demographics of Virginians, including (1) an aging population; [31] (2) 17% of Virginians live in designated primary care physician shortage area[32]; (3) one-third of the state is obese; (4) 34% of the state has high cholesterol; (5) 32% of the state has hypertension;[33] and (6) 50% of Virginians with chronic disease do not take their medications as prescribed.[34] Additionally, the results of the 13-year Virginia Coordinated Care Research Program revealed that a one-size care model does not fit all uninsured Virginians, and that new

[27] Tyrrell R. How Carilion Clinic saved $1.7M by expanding the role of pharmacists. Advisory Board. September 15, 2017. https://www.advisory.com/research/care-transformation-center/care-transformation-center-blog/2017/09/carilion-clinic

[28] Bringing Pharmacies to the Table: Carilion Program Engages Pharmacists in Care Transitions Initiative. Carilion Clinic Awarded CMMI Funding. http://qin.hqi.solutions/wp-content/uploads/2014/12/Carilion_Clinic_Awarded_CMMI_Funding.pdf

[29] A Team-based Care Approach to Reach Rural, Underserved Virginia Patients. WWCDPC. 2018. https://chronicdisease.host/WWCDPC/admin/dompdf/SuccessStories.php?id=712

[30] Health Quality Innovators. A Partnership in Chronic Care Management. http://qin.hqi.solutions/wp-content/uploads/2018/05/CCM-poster-with-3-video-QR-link.pdf

[31] US Census Bureau. QuickFacts: Virginia. 2018. https://www.census.gov/quickfacts/VA

[32] Primary Care Needs Assessment. Virginia Department of Health. http://www.vdh.virginia.gov/content/uploads/sites/76/2016/05/Primary-Care-Needs-Assessment-OHE.pdf

[33] America's Health Rankings. https://www.americashealthrankings.org/learn/reports/2018-annual-report/state-summaries-virginia

[34] Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017.

		models of preventive, acute and chronic care are needed. Moreover, the literature is replete with evidence that pharmacy care is safe and effective, drives patient outcomes, improves quality and access to care, enhances care coordination, and reduces total cost of care.[35,36] For these reasons, and for reasons discussed in our detailed submission of October 1, 2019, NACDS strongly urges JCHC to undertake a comprehensive assessment and modernization initiative regarding pharmacy care laws and policies as one of the critical means to ensuring the health, safety and welfare of Virginians. Creating a robust, efficient and effective healthcare environment that advances patient choice and competition to improve accessibility and health quality, and affordability of healthcare is a win-win proposition for all. By removing the limiting and needless restrictions on the practice of pharmacy in Virginia, pharmacists will be able to deliver care at their fullest practice level across the state; opening healthcare access to care to those in the inner city and rural areas – allowing better health to flourish.
NEW Option 9: Authorize pharmacists to deliver ACIP recommended vaccines for all ages		NACDS also urges JCHC create a synergistic new policy option, Policy Option 9, aimed at removing unnecessary, constraining requirements that force pharmacists to immunize subject to protocol and/or prescription order. Instead, the Commonwealth should expand immunization authority to advance population health in the Commonwealth; especially since CDC notes that many adults go unvaccinated and the agency promotes the use of convenient and accessible health destinations – including community pharmacies to help address this important public health challenge.

[35] Dow A, Bohannon A, et al. The Effects of Expanding Primary Care Access for the Uninsured: Implications for the Health Care Workforce Under Health Reform. December 2013. Academic Medicine.
https://journals.lww.com/academicmedicine/Fulltext/2013/12000/The_Effects_of_Expanding_Primary_Care_Access_for.22.aspx

[36] Retchin S, Dow A. Right-Sizing the Nation's Workforce for the Affordable Care Act. November 5, 2014. Academic Medicine.
http://academicmedicineblog.org/right-sizing-the-nations-workforce-for-the-affordable-care-act/

Prescription Drug Price Gouging

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Senior Health Policy Analyst

Study Request

Senator John Edwards introduced Senate Bill 1308 to prohibit unconscionable price increases of essential off-patent or generic drugs in the 2019 General Assembly session. The legislation was Passed By Indefinitely by the Senate Education and Health Committee chaired by Senator Newman with a letter to the JCHC requesting they study the issue. Commission members approved the study during the May work plan meeting.

Drug Spending Increases

The PIRG Education Fund reported in March of 2019 that drug unit price increases, rather than increased utilization, is driving drug spending. From 2012 - 2016, the price of drugs rose approximately 25% while utilization increased by approximately 2%.[37] A common perception is that the high price of drugs is justified by the cost of research and development, including drugs that do not make it to market, but a Thomson Reuters study found that drug companies spend far more on marketing and advertising than they do on research and development.[38]

Drugs are sold at a variety of prices, depending on where in the supply chain a transaction occurs, manufacturers' rebates, coupons, and clawbacks, and whether the rebates and other discounts are included in published prices.[39] For example, the federal government requires that manufacturers pay rebates for single-source, brand-name drugs that are provided to Medicaid recipients. Also, there are supplemental rebates (beyond the federally-required rebates) that PBMs and carriers negotiate in exchange for inclusion in a preferred drug list and favorable tier placement (which determine preauthorization requirements and patient co-payment amounts).

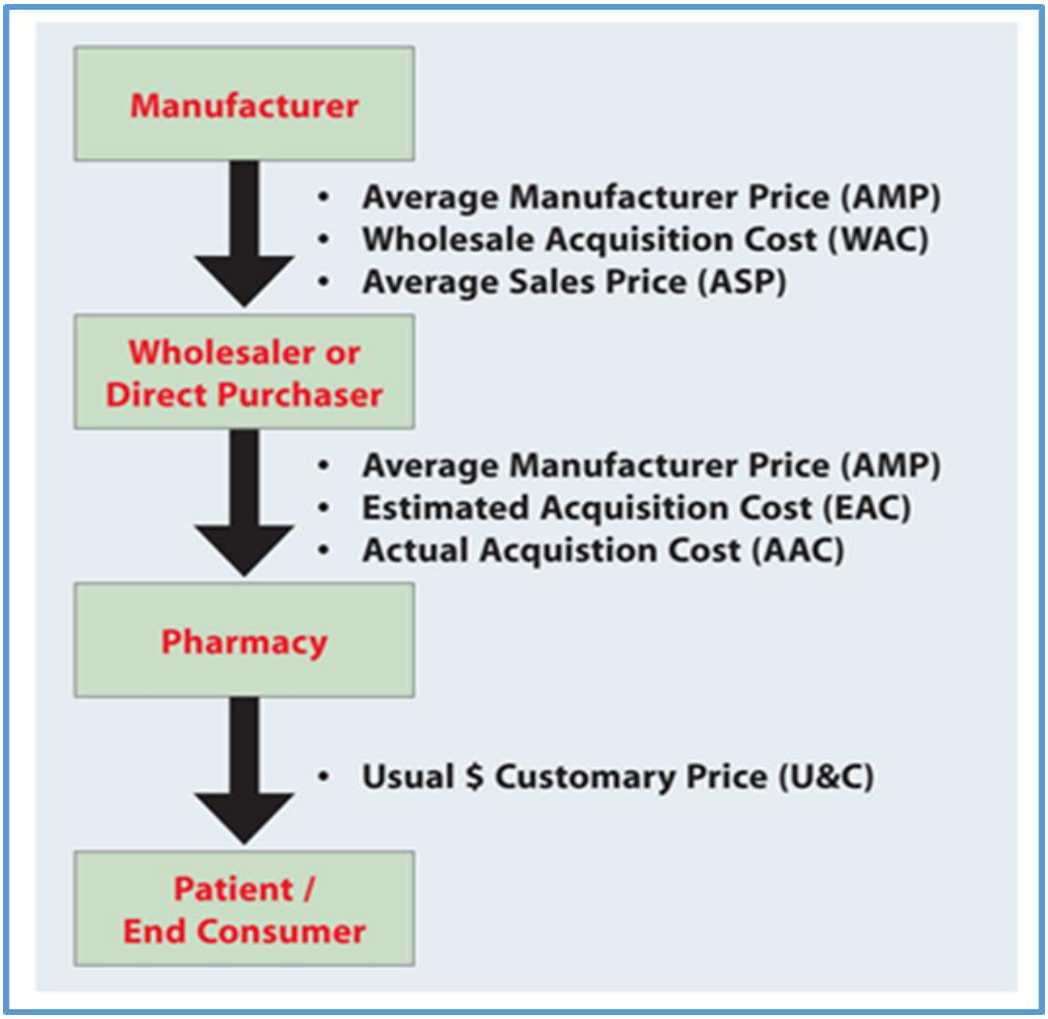
37 The Real Price of Medications - A Survey of Variations in Prescription Drug Prices. Reuben Mathew, Lance Kilpatrick & Adam Garber. U.S. PIRG Education Fund, March 2019.
2 https://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf
39 Excluding rebates in the published price is used to keep prices charged to non-Medicaid plans higher than if the rebates were factored into the price, as an incentive for manufacturers to provide Medicaid rebates.

Figure I: Drug Pricing Terms

Term	Explanation[40]
Average Manufacturer Price (AMP)	A measurement of the price a wholesaler pays for products from the manufacturer after rebates or discounts.
Average Wholesale Price (AWP)	A measurement of the price paid by pharmacies to wholesalers. This is an estimate based on reporting to data vendors.
Wholesale Acquisition Cost (WAC)	An estimate of the manufacturer's list price to wholesalers, it does not include discounts/rebates.
Average Actual Cost (AAC)	The final cost paid by pharmacies to their wholesalers after all discounts have been deducted and is derived from actual audits of pharmacy invoices.
Average Sales Price (ASP)	Derived from the sales from manufacturers to all purchasers and includes most discounts, but is limited in that it is only available for Medicare Part B covered drugs.
Estimated Acquisition Cost (EAC)	An estimated price that state Medicaid programs use to reimburse pharmacies for the cost of the drug plus a reasonable dispensing fee.
Best Price (BP)	The lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, (Medicaid, 340B covered entities, Medicare Part D plans, and certain other purchasers)
Usual and Customary Price (U&C)	The amount charged at a retail pharmacy. It reflects the cost to the consumer without insurance.
Federal rebates	Manufacturers must provide rebates to states in order to sell brand name drugs to Medicaid patients.
Supplemental rebates	Paid in exchange for placement on a Preferred Drug List (PDL) and result in market share shifts to the preferred drug[1], even if the list price is greater than an available alternative.
Price Spread	The difference between the PBM cost and the price the PBM charges the insurer.

[40] https://masspirg.org/sites/pirg/files/reports/MAP%20Rx%20Price%20Report%20March%205.2019.pdf

Figure II: Drug Pricing Along the Distribution Pipeline

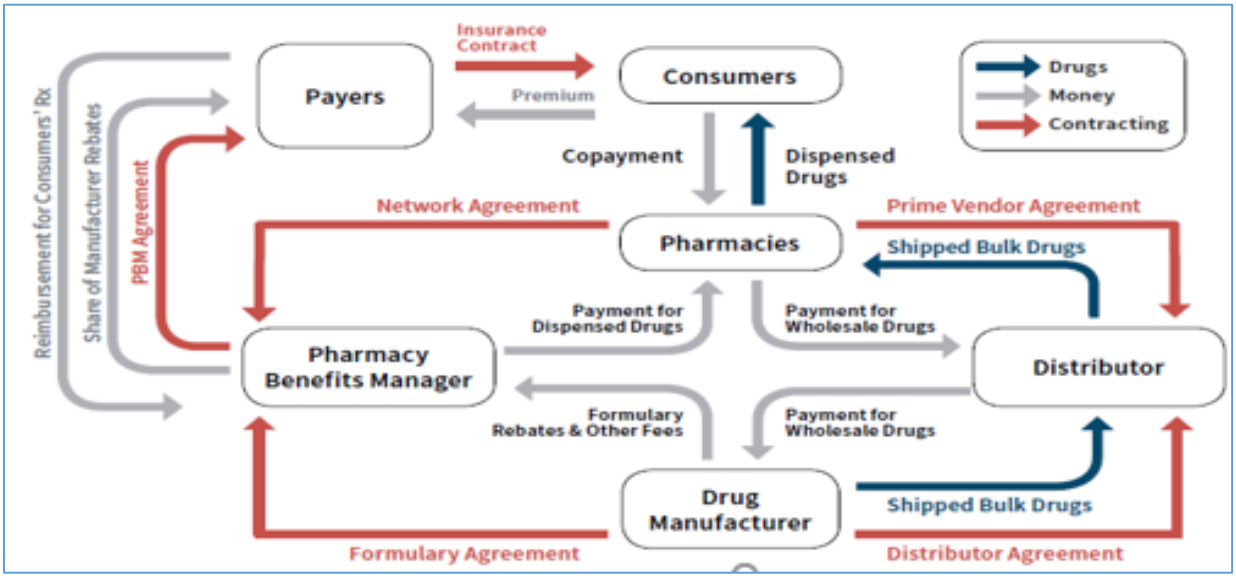


The Drug Distribution and Payment Pipelines

The drug distribution and payment pipelines are extremely complex and lack transparency. Parties in the pipeline include manufacturers, wholesalers/distributers, pharmacy benefit managers, insurers, pharmacies and consumers. Contractual terms between parties, such as the price of a drug or the amount of rebates, may not be revealed to other parties in the pipeline, which may contribute to arbitrage. Some agreements favor the use of brand-name drugs, despite the availability of less expensive generic drugs, because one or more of the parties derives higher profits from selling the more expensive brand name product[41] (e.g., PBMs derive profits in the form of manufacturer rebates).

[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/

Figure III. The Drug Distribution and Payment Pipelines



Pharmacy Benefit Managers (PBM)

Insurance companies often hire PBMs to manage their pharmacy benefit. Ninety-five percent of insured individuals have drug coverage managed by a PBM, and the three largest PBMs control 80% of the market. In addition, several of the largest PBMs are owned by insurance companies.

PBMs receive manufacturer rebates in exchange for placing a drug on the health insurance plan's list of covered drugs, especially if listed as a preferred drug (i.e. having no or low co-payments and/or no pre-authorization requirements). The difference between the payments made by insurance companies to PBMs and the rebates PBMs receive from the manufacturer or wholesaler/distributor is known as *the spread.* The amount of the spread is often unknown by the insurance company.

Some states require that PBMs and insurance companies use *pass-through contracts* rather than spread pricing. Pass-through contracts separate PBM fees paid by the insurer into separate components, for example drug acquisition costs, administrative costs (e.g., pre-authorization and claims adjudication), and PBM profit. Pass-through contracts are more transparent than spread priced contracts as all components of transactions, including profit, are spelled out in the contract. Also, several states are requiring that PBMs work in the best interest of patients and the insurance companies (i.e. *fiduciary duty*).

Virginia insurance industry representatives assert that spread pricing is an appropriate method of ensuring PBM's profitability; however, several states that performed analyses of their Medicaid PBMs found that PBMs using spread pricing contracts were keeping hundreds of millions of dollars a year in rebate money (see Table I). Spread price contracts can encourage the use of drugs that provide rewards to PBMs versus the use of the lowest cost drugs. Profit levels written into PBM pass-through contracts can ensure PBM profitability while also ensuring that the state is acting as a responsible steward of tax-payer funds (for Medicaid plans). For example, the Medallion 4.0 Medicaid managed care organization contracts in Virginia specify that managed care organizations with profits over 8.5% in a contract year must return excess profits to the state.

Table I: State findings of Audits of Medicaid Managed Care Contracts with PBMs.

State	Findings
Ohio	From 4/1/17 – 3/31/18 the spread on drugs in the Medicaid MCO program ranged from 0.8% for branded drugs, 31.4% for generics, and 1.1% for specialty drugs with a total average spread of 8.9%[1]. The average price spread represented **$224.8M** on 39.4 million drug claims. **In 2018, Ohio announced that its Medicaid MCO programs would switch to a pass-through model.**
Kentucky	PBMs that contracted with Kentucky Medicaid MCOs reported being paid $957.7M for spread pricing contracts, **$123.5M of which was kept by the PBMs** in CYs 2018 and 2019 [2.]
Mass	Drug spending in 2012 grew twice as fast as other MassHealth spending. The state noted its concern of the use of spread pricing for generic drugs by PBMs [3.] **In 2014, spread pricing covered 22% of all PBM compensation, but in 2016 that number rose to 54%.** For SFY 2020, Massachusetts officials have proposed a requirement for PBMs to be transparent about pricing and to limit PBM margins under MCO and accountable care organization contracts. **The government projects savings of $10 million.**

[1.] Ohio's Medicaid Managed Care Pharmacy Services Auditor of State Report, August 16, 2018.
[2.] Medicaid Pharmacy Pricing. Kentucky Cabinet for Health and Family Services Office of Health Data Analytics, 2/19/2019.
[3.] https://www.fiercehealthcare.com/payer/massachusetts-puts-transparency-demands-pbms-as-drug-spend-jumps-41

Methods for Addressing High Drug Prices

States are using a variety of methods for slowing the increase in drug costs and are saving money by implementing strategies that target various points in the drug distribution and payment pipelines. Methods include:

- Increasing state authority to regulate PBMs through insurance contracts
- Requiring transparency reports from manufacturers and PBMs
- Subscription-based contracts with manufacturers
- Spending limits and caps
- Requiring notification in advance of price increases over a certain amount and/or for the highest priced and most utilized drugs
- Requiring that PBMs work in the best interest of insurance companies and plan members
- Banning pay-to-delay agreements for creating generic drugs
- Creating drug affordability review boards
- Importing drugs from Canada
- Establishing within-state and across-state purchasing compacts
- Value-based drug payments

Some of these methods require significant amounts of state resources to implement, (e.g., foreign importation) while others are more easily implemented (e.g., PBM requirements).

Pros and Cons of Options to Consider

Option	Pros	Cons
1. Take No Action	• Implementation of some strategies could require significant work and budget allocations. • New strategies could take a year or more to implement. • New federal laws may make state action less necessary.	It is uncertain if any of the proposed federal legislation will become law, or if they do, what the final language will be.
2. Authorize the Bureau of Insurance to license and regulate PBMs through insurance companies.	Would allow the state to mandate elements of PBM activities (e.g., requiring pass-through contracts, transparency reports, prohibit clawbacks and conflicts of interest, etc.).	May require additional staff and a budget appropriation to fund new positions and administrative functions.
3. Require pass-through contracts between PBMs and insurance companies with audit rights (with option 2).	• Pass-through contracts require that PBMs charge insurers the net price of a drug. • Increases transparency and eliminates spread pricing. • Discourages the use of brand-name drugs when cheaper, generic drugs are available.	• The administrative portion of insurers' payments to PBMs could increase to compensate for lower revenue related to the reduction of the use of higher priced brand-name drugs. • May change an insurers' medical loss ratio if previous contracts classified *all* components of PBM payments as medical costs. • If cost-plus reimbursement is used, manufacturers may set higher prices.
4. Require PBMs to submit transparency reports (with option 2).	Reports would include: • Break-out of administrative expenses, drug costs and profits • Financial assistance provided • Rebates • Costs of coupons • Wholesale acquisition cost • 5-year history of increases • Marketing and advertising costs	• May add to administrative costs that are then passed on to employers. • If the information is not confidential could enable tacit collusion. • May give unfair insights into competitors. • May require audits. • May reduce margins on generics undermining incentives to encourage generic utilization.

Option	Pros	Cons
5. Require PBMs to act in the best interest of insurers and their members (with option 2).	• Would provide transparency and discourage hidden arbitrage. • Increased bargaining power of health plans and pharmacies to level the playing field. • Discourage the use of brand name and authorized generics and increase the use of lower cost generic drugs. • Disallow PBMs using lower cost MAC lists to pay pharmacies, higher cost MAC lists to bill insurance companies, and keeping the difference.	• Could require increased monitoring.
6. Prohibit the use of manufactures' coupons.	• May increase price transparency. • The use of coupons can drive shifting from generics to brand name drugs and result in higher insurance premiums.	Coupons may be used by uninsured individuals, or when the coupon lowers the price paid by the consumer to below the insurance copay amount. So patients may perceive this as a price increase, as the use of coupons lowers the cost to the patient at the point of sale.
7. Introduce legislation modeled after CA to ban pay-to-delay. (Regulation signed into law Oct. 2019).	Could accelerate the pipeline for generic drugs.	Would require resources of the Office of the Attorney General and possible budget appropriation for the increased resource need.
8. Develop a program to import drugs from Canada.	• Imported drugs would be less expensive. • Supported by the Trump Administration and CMS. • Imported drugs would be safe. • The drug market is already a global market.	• Canada has released statements of opposition, citing concern about drug shortages in their country. • Would take significant state resources and time to craft/pass legislation and implement a program. • A budget appropriation may be needed for administrative costs.

Option	Pros	Cons
9. Develop a subscription model for purchasing Hepatitis C and other drugs for Medicaid members and incarcerated individuals.	• Could expand access to treatment and lower the price of Hepatitis C drugs. • Could help prevent the spread of Hepatitis C. • Could be expanded to include diabetes and other appropriate drugs.	• The model only works if there is unmet need. • The lack of providers trained in treating Hepatitis C would need to be addressed (Project Echo may be a solution). • Hepatitis C testing costs would increase. • Significant state resources and time to craft/pass legislation and implement a program. • May need budget appropriation to pay administrative costs.
10. Implement a Drug Affordability Board and Upper Payment Limits, such as Maryland, Maine, New York and Vermont.	• Imposes transparency. • Would help set fair, affordable prices.	• Would take significant state resources and time to craft/pass legislation and implement a program. • A budget appropriation to pay administrative costs would be needed.

Public Comments and Policy Options

Comments were received from the following 12 stakeholders:

- Doug Grey, Executive Director**, Virginia Association of Health Plans**, (**VAHP**)
- Shannon Wood, Senior Manager, Advocacy, **National Multiple Sclerosis Society** (**NMSS**).
- Tara C.F. Ryan, Vice President of Government Affairs, **Association for Accessible Medicines (AAM).**
- Christina Burrill, Executive Director, **Virginia Pharmacists Association,** (**VPhA**).
- R. Scott Woods, Assistant Vice President, State Affairs, **Pharmaceutical Care Management Association, (PCMA).**
- Angela Gochenaur, Eastern Director, State Government Affairs, The **Biotechnology Innovation Organization (BIO).**
- Nicole Palya Wood, Senior Regional Director, Anne Leigh Kerr, President, Kerr Government Strategies (on behalf of PhRMA), and Julia Worcester, Director of State Affairs Pharmaceutical Researchers and Manufacturers of America, (**PhRMA**)
- Patricia G. Robinson, Rph. (**PR**).
- Wayne D. Wilson, Vice President, Government Programs and External Relations **Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.** (**KP**).
- John Newby, CEO, **VirginiaBio**, (**VB**).
- Teresa H. Powers, Retail Pharmacist, (**TP**).

- John Droblyn, PharmD, Eagle Pharmacy (**JD**).

  Comments from the following could not be linked to any policy options
- Travis Hale, PharmD**,** President, Apothecary Solutions Inc.
- Peter Zapf

Option	Support/Neutral	Oppose
1.  **6-3** Take No Action	1 PhRMA	JD
2. BOI regulate PBMs through insurance companies **8-2 FAILED**	2 NMSS, PhRMA	0
3. Require PBM pass through contracts **8-2 FAILED**	4 NMSS, TP, PhRMA, PR	3 VAHP, PCMA
4. Require PBM transparency reports **8-2 FAILED**	4 PhRMA, NMSS, TP, PCMA	3 VAHP, PhRMA
5. PBMs fiduciary duty	3 NMSS, VPhA, PhRMA	0
6. Ban Coupons	1 KP	2 NMSS, BIO
7. Ban pay-to-delay **8-2 FAILED**	3 NMSS, KP, VB	3 AAM, BIO, PhRMA
8. Importation program **8-2 FAILED**	1 VB	2 BIO, PhRMA
9. Subscription model	1 PhRMA	0
10. Affordability Board	4 NMSS, VPhA, KP, VB	3 VAHP, AAM, BIO

Summary of Public Comments

Commenter	Supports (Option #)	Opposes (Option #)
Virginia Association of Health Plans		• Requiring pass-through contracts (3). • Greater state oversight of PBM contracts (4).
Pharmaceutical Care Management Association	Spread pricing transparency tools for physicians regarding price and cost-sharing, PBM contract terms to all clients, and information on price concessions, costs and service fees to Medicare Part D federal regulators.	Requiring pass-through contracts with audit rights (3).

Association for Accessible Medicines	Policies that ensure utilization of lower cost biosimilars rather than driving increased rebates from brand biologics.	• Prohibition of pay-to-delay (7). • Drug affordability board (at least until Maryland and Maine have fully implemented their Boards and reports are published regarding their effectiveness in curtailing costs.) (10). • Drug spending caps like those in New York.

Commenter	Supports (option #)	Opposes (option #)
National Multiple Sclerosis Society	• State-level action to address high prescription drug costs and accessibility. • Increased regulation of, and transparency for, PBMs (2, 4). • Make certain the rebates are passed on to the consumer. • Require PBMs to act in the best interest of insurers and consumers (5). • Banning pay-to-delay and other practices that prevent generics from getting to people that need them (7). • PBM transparency reports from manufacturers who increase drug prices by 10% per year or more than 25% over a three-year look back period and justification for such increases (4). • Notification from manufacturers to states and consumers when bringing a drug to market with a high launch price (4). • Establishment of a drug affordability board (10).	Prohibition of manufacturers' coupons (6).
Virginia Pharmacists Association	• Increased PBM oversight and regulation to curtail *take-it-or-leave-it* contracts, a lack of transparency, underwater reimbursements to pharmacists, retaliatory pharmacy audits, limited appeals processes, retroactive fees (clawbacks) (10). • Require that PBMs have a fiduciary duty to health plans, plan sponsors and to the state (5).	

Biotechnology Innovation Organization		• Prohibition of pay-to-delay (7). • Prohibition of manufacturers' coupons (6). • Drug importation from other countries (8). • Drug affordability board and upper payment limits (10). • Single state efforts rather than national solutions (1).

Commenter	Supports (option #)	Opposes (option #)
PhRMA	• Neutral or supports Options 1 through 5 and 9. • States' efforts to explore voluntary financing arrangements, such as the subscription model used in Louisiana (9).	• Prohibiting cost sharing assistance (coupons) (6). • Importation from Canada (8). • Delay a Drug Affordability Boards (10). • Prohibition of pay-to-delay contracts (7). • Transparency reports (4).
Patricia B. Robinson, Rph.	Banning spread pricing (3).	
Kaiser Permanente	• Banning spread pricing contracts (3). • Banning pay-to-delay contracts (7). • Banning manufacturers coupons (6). • Neutral on Drug Affordability Boards with considerations (10).	• Pass-through contracts with audit rights (3). • PBM transparency reports (4).
VirginiaBio	• Banning pay-to-delay contracts (7). • Drug importation (8). • Drug Affordability Boards and upper payment limits (10).	
Teresa H. Powers, retail pharmacist	• Transparency (4). • Banning spread pricing (3).	
John Droblyn, retail pharmacist	Did not address specific policy options, but dislikes low reimbursements from PBMs, clawbacks and DIR fees. "Transparency is only 1st step."	