JOINT COMMISSION ON HEALTH CARE

Senator Rosalyn R. Dance, Chair
Delegate T. Scott Garrett, Vice Chair

January 8, 2020

Senator Stephen D. Newman
Senate Health and Education Chair
P.O. Box 480
Forest, Virginia 24551

Dear Senator Newman,

As requested, please see the attached written report of study summaries for following:

- Senate Bill 1741- Language Development Milestones and Parent Resources for Young Deaf/Hard of Hearing Children
- House Bill 2223- Increased Prescription Delivery Options at Same Cost for Health Plan Members
- Senate Bill 1308- Prescription Drug Price Gouging

If you have any questions or require anything further, I may be reached at mchesser@jchc.virginia.gov or 804-786-5445.

Michele Chesser

Michele L. Chesser, Executive Director
Joint Commission on Health Care

cc: Susan Clarke Shaar, Senate Clerk
Delegate Israel D. Quinn
Senator John S. Edwards
Mark Vucci, Director, Division of Legislative Services

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

2019 Report Summaries for Studies Requested by Senate Education and Health

Code of Virginia § 30-168.

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

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

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

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STAFF REPORTS

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

Andrew Mitchell, ScD
Senior Health Policy Analyst

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.

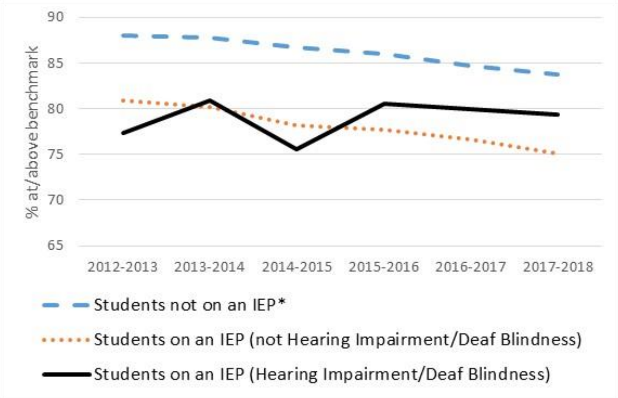
In Virginia, six State agencies support D/HH children through screening/diagnosis, developmental /education services and family support. The following are the three primary services and supports.

- 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).

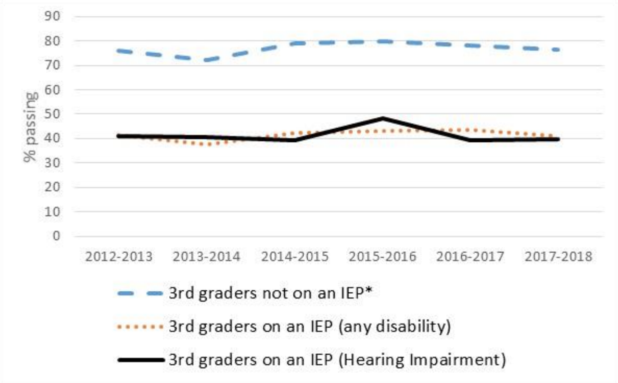
Language development among D/HH children 0-5 years old in Virginia is not directly measured. However, beginning in preschool, achievement in *literacy* is measured by VDOE through Phonological

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)

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[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	

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[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

<u>WE DO NOT SUPPORT</u>

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."

Prescription Drug Price Gouging

Paula Margolis, PhD, MPH,
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%.[4] 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.[5]

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.[6] 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).

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4 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

6 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[7]
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.

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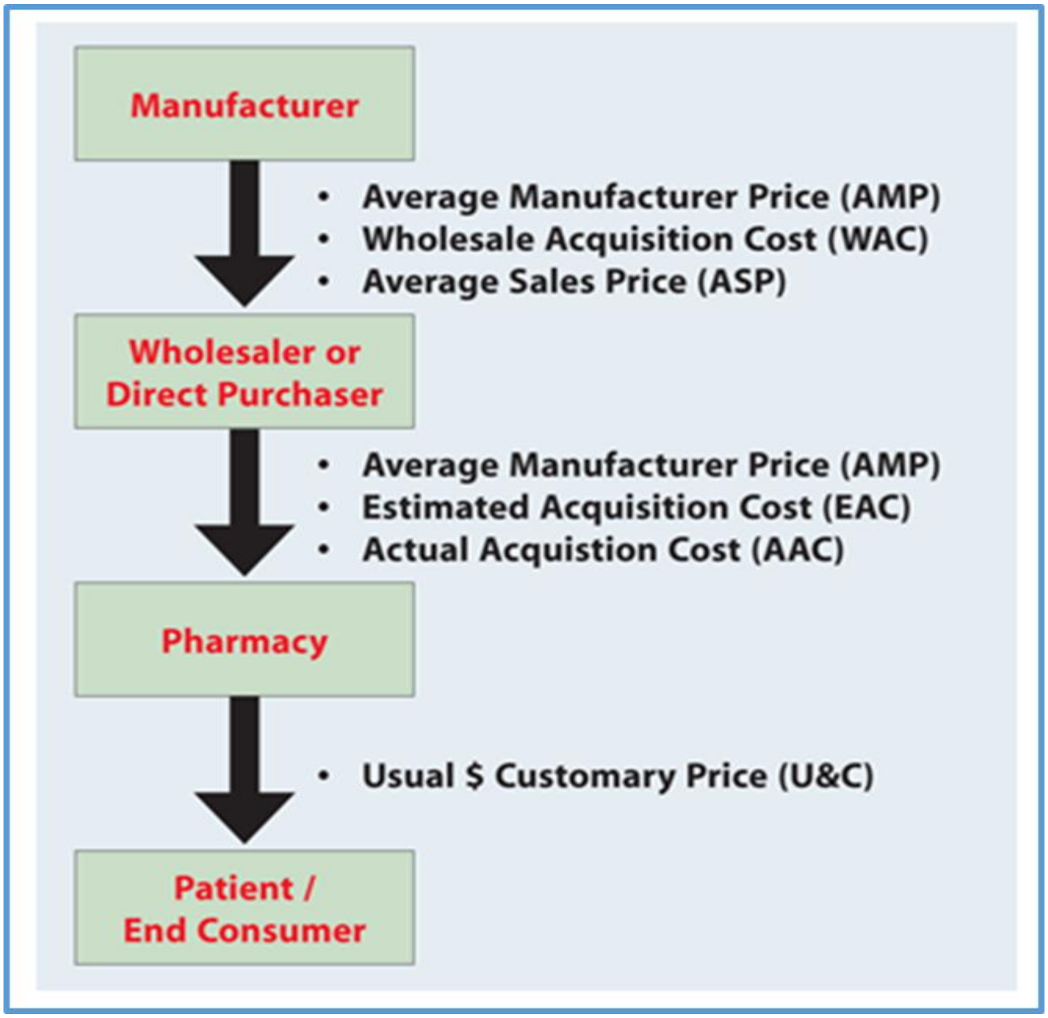
[7] https://masspirg.org/sites/pirg/files/reports/MAP%20Rx%20Price%20Report%20March%205.2019.pdf

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[8] (e.g., PBMs derive profits in the form of manufacturer rebates).

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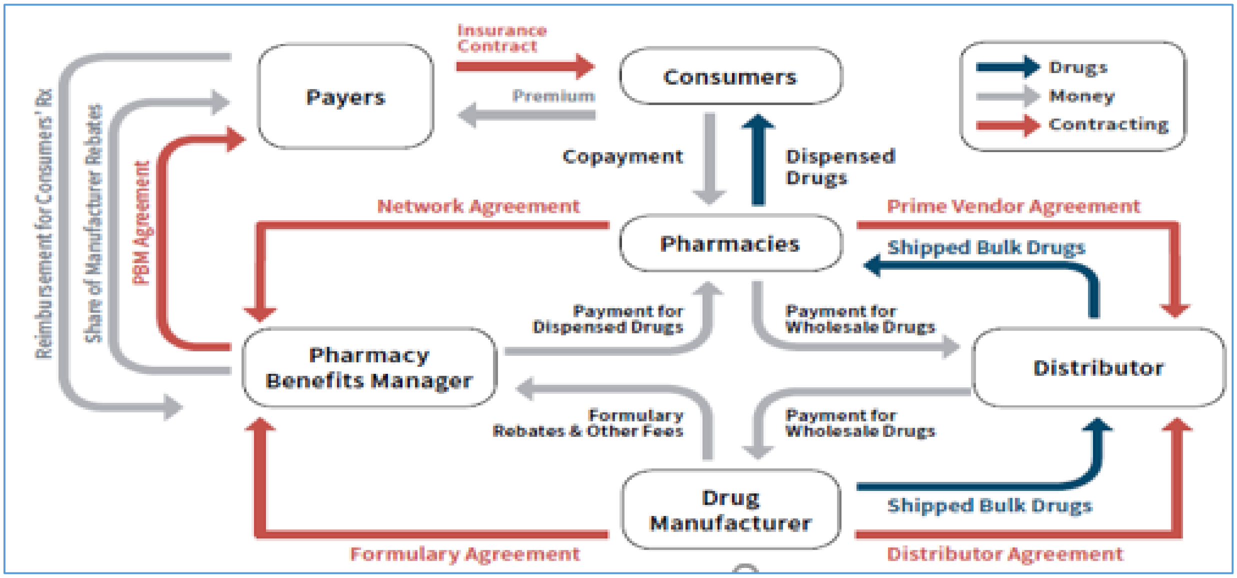
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/

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).

Commenter	Supports (Option #)	Opposes (Option #)
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.
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).	

Commenter	Supports (Option #)	Opposes (Option #)
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).
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."	