Study Information Forms

For

2019 Studies

Joint Commission on Health Care

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

SOURCE OF STUDY MANDATE:

House Joint Resolution 662 (patrons: Delegates Christopher P. Stolle and Alfonso H. Lopez) directs the Joint Commission on Health Care to study the dispensing of prescription drugs and devices pursuant to pharmacy collaborative practice agreements (CPAs), standing orders, and statewide protocols in the Commonwealth, including a review of the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices in accordance with laws and regulations. The resolution, as amended, passed in the House and Senate and was enrolled February 22, 2019.

SUMMARY:

The JCHC is directed to study the dispensing of drugs and devices pursuant to prescriptions, pharmacy CPAs, standing orders, and statewide protocols in the Commonwealth, including:

- Evaluate laws and regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth, including those pursuant to pharmacy CPAs, standing orders, and statewide protocols;
- Review the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing and administering drugs and devices, including the evaluation of the roles and responsibilities of pharmacists who are authorized to practice pursuant to pharmacy CPAs, standing orders, and statewide protocols, conduct patient assessments, and identify appropriate drugs or devices for dispensing or administration;
- Determine the legal liability of pharmacists and other health care providers pursuant to CPAs, standing orders, and statewide protocols;
- Identify any changes to such laws or regulations governing the prescribing, dispensing and administration of drugs and devices pursuant to pharmacy CPAs, standing orders, and statewide protocols that would enhance patient access to health care in the Commonwealth;
- Develop specific proposals to implement identified changes, including amendments to laws and regulations necessary to implement such changes;
- Provide for stakeholder input from the Department of Health, the Department of Health Professions, the Medical Society of Virginia, and the Virginia pharmacists Association.

HAS TOPIC BEEN STUDIED IN THE POLICY ARENA IN VIRGINIA, OR IN OTHER STATES, IN THE LAST 10 YEARS?

YES __X__ NO ____.

ADDITIONAL INFORMATION:

While no Virginia studies of the topic were found during a preliminary search of the literature, there is a great deal of information on CPAs from other states, the Centers for Disease Control and Prevention, policy organizations, and journal publications. Some of these materials provide recommendations for states wishing to streamline administrative requirements for the use of CPAs. Several guides, white papers and presentations include statistical information from other states. Finally, there are a number of journal articles examining the use of CPAs in specific health conditions such as diabetes, oncology-

based symptom management, stem cell transplant and cardiovascular care; and, a 2009 report provides outcomes research in Maryland. Additional information will likely be discovered after a more thorough search of the literature.

DRAFT WORK PLAN FOR STUDY:

- Review and evaluate:
  - The prescribing, dispensing and administration of drugs and devices pursuant to PCPAs, standing orders, and statewide protocols
  - Regulation governing PCPAs
  - Roles and responsibilities of pharmacists and other health care providers
  - Scope of practice issues – Some NPs and PAs can now practice independently in Virginia. Should they be allowed to enter into a PCPA as the provider?
  - Potential changes to laws or regulations governing the dispensing and administration of drugs and devices pursuant to a PCPA
  - Legal liability
- Federal rules regarding PCPAs related to Medicare and Medicaid
- Contact the Board of Pharmacy to get clarification on the current state of practice; how non-standard practice guidelines are submitted and approved, the scope of PCPAs currently in Virginia, what is/isn't working well, and what should be changed.
- Research other state's and health policy organization's resources regarding PCPAs, including laws and regulations.
- Research operational issues including:
  - Contract specifications
  - Communications between pharmacy and prescriber
  - Safeguards
  - Financing and payment issues - costs to prescriber and pharmacy - sustainability
  - How PCPAs interface with third-party payers (insurance; public, private, self-funded, marketplace plans)
  - Quality monitoring
  - Pharmacy collaborations with hospitals to help with transition after discharge to prevent readmissions
- Solicit input from the following:
  - Virginia Department of Health
  - Virginia Department of Health Professions
  - Virginia Board of Pharmacy
  - Medical Society of Virginia
  - Virginia Pharmacists Association
  - Virginia Council of Nurse Practitioners
  - Virginia Academy of Physician Assistants
  - The Department of Medical Assistance Services
  - Virginia Association of Health Plans
  - Virginia Society of Health System Pharmacists
  - Virginia Association of Chain Drug Stores
  - National Alliance of State Pharmacy Associations
- Develop proposals to implement needed changes, if any, identified by the research

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): high.

Prescription Drug Price Gouging Prohibited

SOURCE OF STUDY REQUEST:

Senate Bill 1308, submitted by Senator John S. Edwards, was *passed by indefinitely* on January 24, 2019 in the Education and Health Committee with the understanding that the subject matter contained in the bill would be referred to the Joint Commission on Health Care for study. The Committee members also requested that the study report be submitted to the Chair of the Education and Health Committee, the bill patrons and the Office of the Senate Clerk by November 1, 2019.

SUMMARY:

The bill language would: authorize the Secretary of Health and Human Resources to designate drugs as essential, prohibit unconscionable price increases, establish an enforcement mechanism, and mandate that the Director of the Department of Medical Assistance Services (DMAS) notify the Attorney General of an increase in the price of an essential off-patent or generic drug. An essential off-patent or generic drug is defined as a prescription drug

(i) for which all exclusive marketing rights granted under the federal Food, Drug and Cosmetic Act and federal patent law have expired;

(ii) that appears on the most recently adopted *Model List of Essential Medicines* published by the World Health Organization or that has been designated by the Secretary as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic condition that substantially impairs an individual's ability to engage in activities of daily living;

(iii) that is actively manufactured and marked for sale in the United States by three or fewer manufacturers; and

(iv) that is made available for sale in the Commonwealth.

An essential off-patent or generic drug also includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights granted under the federal Food, Drug, and Cosmetic Act §351 of the federal Public Health Act, and federal patent law have expired.

SB 1308 mandated that the Director of the Department of Medical Assistance Services notify the Attorney General of an increase in the price of an essential off-patent or generic drug if:

-the increased price, alone or in combination with other price increases, would result in a price increase of 50 percent or more in the wholesale acquisition cost (as defined in 42 U. S. Code §1395w-3a)[1] of the drug, as compared with the wholesale acquisition price[2] for the same drug prior to the increase, or the price paid by DMAS for the drug prior to the increase;

[1] The wholesale acquisition cost (WAC) means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale prices guides or other publications of drug or biological pricing data.

[2] The term *wholesale acquisition price* is not found in the literature or online search and is suspected to be a typo; we believe that the correct term may be *average manufacturer price,* or *wholesale average price*. Both of these terms are defined in federal law (there are other terms that include the word *price* defined in federal law).

-the cost of a 30-day supply of the maximum recommended dosage of the drug for any indication approved by the U.S. Food and Drug Administration would cost more than $80 at the WAC, or;

-in cases in which the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment of the drug would exceed $80.

A list of all drugs identified as essential drugs for the purpose of this chapter shall be posted on a website maintained by the Department of Medical Assistance Services.

Upon receipt of notification of suspected price gouging pursuant to § **32.1-330.6** or in any other case in which the Attorney General has reasonable cause to believe that any person has engaged in, is engaging in, or is about to engage in any violation of this chapter, the Attorney General is empowered to issue a civil investigative demand.

HAS TOPIC BEEN STUDIED IN THE POLICY ARENA IN VIRGINIA, OR IN OTHER STATES, IN THE LAST 10 YEARS?

YES _X_ NO ____.

ADDITIONAL INFORMATION:

The issue of drug price gouging has garnered a great deal of interest over the past several years, at both state and federal levels. Maryland passed a law in 2017 that prohibited generic drug manufacturers from raising prices in a manner the state deemed *unconscionable* that was ruled unconstitutional by the U.S. Fourth Circuit Court of Appeals. The Court held that Maryland's law overstepped limits on how states can regulate commerce, specifically on states controlling business that takes place outside their borders.[3] The ruling was appealed to the U. S. Supreme Court which denied to hear the case on February 19, 2019. According to Senator Edwards, the Virginia bill was modeled after the 2017 Maryland bill.

Per communications with Senator Edwards' staff, he would like to pursue the original intent of the bill with the power to investigate using subpoena duces tecum[4], but he would like to consider alternatives as well, as the Virginia Attorney General's office conveyed that SB 1308 as worded may not withstand scrutiny in the courts.[5] In addition, Senator Edwards conveyed that it is desired that the bill apply to prescriptions drugs and drug-device combination products covered by private health insurance, not only to drugs covered by DMAS. The Maryland bill applies only to Medicaid, any state health plan and any state health program expenditures.[6,7]

As the bill is written, the method used to calculate price increases that would meet the criteria is unclear. Drug pricing is very complex; included in the complexity is the fact that Virginia Medicaid contracts with a third-party to administer drugs provided to individuals enrolled in the fee-for-service program. The majority of Medicaid enrollees in Virginia are covered under a DMAS-contract managed

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Average manufacturer price is the term used in the Maryland legislation, although it was struck in the final version of the bill: http://mgaleg.maryland.gov/2017rs/bills_noln/hb/thb0631.pdf.

[3] United States Court of Appeals for the Fourth Circuit No. 17-2166 states that the manufacturers typically sell their products to wholesale pharmaceutical distributors, none of which are based in Maryland. The vast majority of these sales occur outside Maryland's borders.

[4] Subpoena duces tecum is a writ ordering a person to attend a court and bring relevant documents.

[5] Per email communication with Luke Priddy, Senator Edwards' Legislative Aide on April 24, 2019.

[6] Per a conversation with Senator Edwards on April18, 2019.

[7] http://mgaleg.maryland.gov/2017RS/fnotes/bil_0001/hb0631.pdf

care organization (MCO) which provides drugs; many, if not all, of the Medicaid MCOs may also contract with a third-party pharmacy benefits manager to administer the drugs they cover. The Centers for Medicare and Medicaid services has comparison drug pricing on line, but the data represents national prices; they are not state-specific. It is unclear if the intention of the bill is to use national or statewide data. Also, in order to participate in Medicaid, drug manufacturers must provide rebates and in some cases, supplemental rebates to the states; research may be needed to determine if and how rebates paid to the state would be factored into pricing information.

There is a great deal of material on the topic from policy organizations, the news media and state websites. Several other states have introduced legislation attempting to address rapidly increasing drug prices and price gouging. In addition, federal legislation was proposed by Senators Sherrod Brown (D-OH) and Kristen Gillibrand (D-NY) on February 7, 2019 that would penalize pharmaceutical companies that engage in price gouging without cause. One recent trend to attempt to rationalize drug spending is to use *value-based pricing* for determining drug costs, and another trend is for states to attempt to increase transparency of drug pricing through legislation.

DRAFT WORK PLAN FOR STUDY:

- Research the fate of legislation attempting to curtail price gouging introduced in other states and the bill language used.
- Follow legislation introduced in the U. S. Congress and report on activity that occurs prior to November 2019.
- Discuss with the DMAS Director, or her representative, the requirement in SB 1308 that she report certain price increases to the state Attorney General, including whether additional funding would be required to track the data longitudinally for each of the Medallion 4.0, CCC Plus, GAP, etc. managed care organizations and the fee-for-service group and create reports.
- Contact the Bureau of Insurance to discuss applying the bill to private health insurance plans.
- The study plan would include further communication with the bill patron and a representative of the Office of the Attorney General to discuss the legal actions, if any, that may be taken by the Attorney General when gouging is found as a result of the civil investigative demand.
- Staff will research other options for addressing prescription drug price gouging that will withstand legal challenges.
- Acquire input from the Bureau of Insurance regarding drug pricing data from private plans sold in the Commonwealth.
- Consideration could be required if laws that allow for out-of-state insurance policies to be sold in Virginia are passed.
- Determine if the bill requires wording to exclude Title XXI (Medicare).

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): Medium to high

Language Development for Children who are Deaf or Hard of Hearing and Assessment Resources for Parents and Educators

SOURCE OF STUDY REQUEST:
Senate Bill 1741 was introduced by Senator Edwards during the 2019 General Assembly session. The bill was referred to the Senate Education and Health committee where it was passed by indefinitely with the understanding that the subject matter would be referred to the Joint Commission on Health Care for study. In the referral letter, received by the JCHC chair, the Senate Clerk requests that a report be submitted to the Chair of the Education and Health Committee, the bill patron, and the Office of the Senate Clerk by November 1, 2019.

SUMMARY (as introduced; see last section of SIF for full text of bill):
Requires the Virginia Department of Behavioral Health and Developmental Services (DBHDS), in coordination with the Virginia Department of Education (DOE) and the Department for the Deaf and Hard-of-Hearing (DDHH), to (i) select, with input from an advisory committee that the bill establishes, language development milestones and include such milestones in a resource for use by parents of a child from birth to age five who is identified as deaf or hard of hearing to monitor and track their child's expressive and receptive language acquisition and developmental stages toward English literacy; (ii) disseminate such resource to such parents; (iii) select existing tools or assessments for educators for use in assessing the language and literacy development of children from birth to age five who are deaf or hard of hearing; (iv) disseminate such tools or assessments to local educational agencies and provide materials and training on their use; and (v) annually produce a report that compares the language and literacy development of children from birth to age five who are deaf or hard of hearing with the language and literacy development of their peers who are not deaf or hard of hearing and make such report available to the public on its website.

HAS TOPIC BEEN STUDIED FOR VIRGINIA GOVERNMENT, OR IN OTHER STATES, IN THE LAST 10 YEARS?
YES _____ NO ___X___.

ADDITIONAL INFORMATION:
A variety of communication options are currently available for children who are deaf or hard-of-hearing. These include forms of oral communication – such as lip reading and maximizing children's own hearing capacities (e.g., through Cochlear implants) – manual communication – such as American Sign Language or other forms of signed language – and combined modes of communication – such as "cued speech" in which hand gestures are used simultaneously with speaking.[8]

Some U.S. states have enacted statutes known as "Language Equality and Acquisition for Deaf Kids" (LEAD-K) laws that are focused on ways to improve access to language and kindergarten readiness for deaf children. These statutes generally create an advisory body to determine ways to improve language acquisition and school readiness, with some requiring the creation of developmental milestones as a reference for parents. States with LEAD-K laws include: California, Hawaii, Kansas, Oregon, South Dakota, Georgia and Louisiana.[9]

[8] http://www.vdh.virginia.gov/content/uploads/sites/109/2016/08/Communication-Options-for-a-Child-who-is-Deaf-or-Hard-of-Hearing.pdf
[9] https://www.cde.ca.gov/sp/ss/dh/sb210langmilestones.asp

In Virginia, at least nine bills since 2017 have been introduced to create an advisory committee focused on readiness of deaf and hard-of-hearing children for kindergarten.[10] Similar to LEAD-K laws in other states, several of those bills – including SB 1741 – mandated that the advisory committee create developmental milestones to be disseminated through the DOE as a parental resource, as well as fund ongoing data collection efforts. However, none of those bills passed in the General Assembly.

DRAFT WORK PLAN FOR STUDY:

- Collect Virginia data on:
    - # children 0-5 years of age diagnosed as deaf/hard-of-hearing (VDH; newborn screening programs)
    - # children 5+ years of age diagnosed as deaf/hard-of-hearing in public schooling system (DOE)
    - Language and literacy development of children 0-5 years of age who: 1) are deaf/hard-of-hearing; and 2) are not deaf/hard-of-hearing. (some data on children who are deaf/hard-of-hearing are reported in compliance with the federally required state performance plan on students with disabilities) (DOE/DBHDS)
- Review literature on:
    - Language/communication acquisition outcomes of deaf/hard-of hearing children 0-5 years of age who receive varying forms of instruction (e.g., signed language only; oral communication only; combined forms of communication)
    - LEAD-K laws in other states
- Convene workgroup consisting of stakeholders listed below – as well as any others, as appropriate – to discuss issues raised in SB 1741. The workgroup will meet 3 – 4 times in 2019, with the goal of identifying points of consensus and considering alternatives to points of disagreement relating to issues raised in Senate Bill 1741.

Stakeholders to contact:

- American Sign Language Teachers Association
- American Society for Deaf Children
- Beginnings
- CueSigns, Inc.
- DBHDS
- Deaf Grassroots Movement
- Disability Commission
- Disability Law Center of Virginia
- DOE
- Hands & Voices
- Infant & Toddler Connection of Virginia
- Language Equality and Acquisition for Deaf-Kindergarten Ready
- Laurent Clerc National Deaf Education Center
- National Alexander Graham Bell Association

[10] The bills were: HB 118 (2018), HB 232 (2018), HB 848 (2018), HB 893 (2018), HB 1410 (2018): Left in HWI; HB 1873 (2017): Left in Ed; SB 160 (2018-2019): left in Ed & Heath; SB 983 (2017): Stricken at patron's request; SB 1741 (2019): PBI'd in Sen Ed & Health with letter

- National American Sign Language and Early Childhood Education Bilingual Consortium
- National Association of the Deaf
- National Black Deaf Advocates
- North Virginia Resource center for Deaf and Hard of hearing Persons
- Ski Hi Deaf Mentor Program
- Speech-Language-Hearing Association of Virginia
- VCU Partnership for People with Disabilities (Center for Family Involvement)
- VDH (Virginia Early Hearing Detection and Intervention Program Advisory Committee)
- Virginia Association of the Deaf
- Virginia Board for People with Disabilities
- Virginia Department for the Deaf and Hard of Hearing
- Virginia School for the Deaf and the Blind (Board of Visitors)

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): Medium-High – based on workgroup component of study

SB 1741 AS INTRODUCED – TEXT

SENATE BILL NO. 1741

Offered January 17, 2019

A BILL to amend the Code of Virginia by adding in Article 1 of Chapter 3 of Title 37.2 a section numbered **37.2-314.1**, relating to language development for children who are deaf or hard of hearing; assessment resources for parents and educators; advisory committee; report.

Patron-- Edwards

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 1 of Chapter 3 of Title 37.2 a section numbered **37.2-314.1** as follows:

§ **37.2-314.1**. Language development for children who are deaf or hard of hearing; assessment resources for parents and educators; advisory committee; report.

A. For the purposes of this section, "language developmental milestones" means milestones of development aligned to the existing instrument used to assess the development of children with disabilities pursuant to federal law.

B. The Department, in coordination with the Department of Education and the Department for the Deaf and Hard-of-Hearing, shall establish an advisory committee for the purpose of soliciting input from members on the selection of language developmental milestones for inclusion in a resource for use by parents of a child from birth to age five who is identified as deaf or hard of hearing to monitor and track the child's expressive and receptive language acquisition and developmental stages toward English literacy. The advisory committee shall consist of 13 nonlegislative citizen members, the majority of whom shall be deaf or hard of hearing and all of whom shall have experience in the field of education of individuals who are deaf or hard of hearing. The advisory committee shall include:

1. One parent of a child who is deaf or hard of hearing and who uses the dual languages of American Sign Language and English;

2. One parent of a child who is deaf or hard of hearing and who uses only spoken English, with or without visual supplements;

3. One parent of a child who is deaf or hard of hearing and who uses only spoken language, with cued visual supplements.

4. One credentialed teacher of students who are deaf or hard of hearing and who use the dual languages of American Sign Language and English;

5. One credentialed teacher of students who are deaf or hard of hearing who teaches at an accredited private, nonsectarian elementary or secondary school;

6. One expert who researches language outcomes for children who are deaf or hard of hearing and who use the dual languages of American Sign Language and English;

7. One expert who researches language outcomes for children who are deaf or hard of hearing and who use spoken English, with or without visual supplements;

8. One credentialed teacher of students who are deaf or hard of hearing whose expertise is in curriculum and instruction in the dual languages of American Sign Language and English;

9. One credentialed teacher of students who are deaf or hard of hearing whose expertise is in curriculum and instruction in spoken English, with or without visual supplements;

10. One advocate for the teaching and use of the dual languages of American Sign Language and English for children who are deaf or hard of hearing;

11. One advocate who is an oral-aural specialist for children who are deaf or hard of hearing;

12. One early intervention specialist who works with infants and toddlers who are deaf or hard of hearing using the dual languages of American Sign Language and English; and

13. One credentialed teacher of students who are deaf or hard of hearing whose expertise is in American Sign Language and English language assessment.

C. No later than March 1, 2020, the Department, in coordination with the Department of Education and the Department for the Deaf and Hard-of-Hearing, shall provide the advisory committee established pursuant to subsection A with a list of all existing language developmental milestones from standardized norms and any relevant information regarding such language developmental milestones for possible inclusion in the parent resource set forth in subsection D. No later than June 1, 2020, the advisory committee shall recommend language developmental milestones for inclusion in the parent resource and may make recommendations for tools or assessments to be included in an educator resource set forth in subsection E for use in assessing the language and literacy development of children from birth to age five who are deaf or hard of hearing. No later than June 30, 2020, the Department, in coordination with the Department of Education and the Department for the Deaf and Hard-of-Hearing, shall select language developmental milestones for inclusion in the parent resource and inform the advisory committee of its selections.

D. The Department, in coordination with the Department of Education and the Department for the Deaf and Hard-of-Hearing, shall, after considering the recommendations submitted by the advisory committee, select language developmental milestones for inclusion in a resource, and develop such resource, for use by parents of a child from birth to age five who is identified as deaf or hard of hearing to monitor and track the child's expressive and receptive language acquisition and developmental stages toward English literacy. Such parent resource shall:

1. Be appropriate for use, in both content and administration, with children who use American Sign Language, English, or both;

2. Present the language development milestones selected pursuant to subsection B in terms of typical development of all children in a particular age range;

3. Be written for clarity and ease of use by parents;

4. Be aligned to the Department's and Department of Education's existing infant, toddler, and preschool guidelines, the existing instrument used to assess the development of children with disabilities pursuant to federal law, and state standards in English language arts;

5. Make clear that parents have the right to select American Sign Language, English, or both, for their child's language acquisition and developmental milestones;

6. Make clear that the parent resource is not a formal assessment of language and literacy development and that parents' observations of their child may differ from formal assessment data presented at an Individual Family Service Plan (IFSP) or Individualized Education Program (IEP) meeting;

7. Explain that parents may bring the parent resource to an IFSP or IEP meeting for purposes of sharing their observations about their child's development; and

8. Include fair, balanced, and comprehensive information about American Sign Language and English and respective communication modes as well as available services and programs.

The Department, the Department of Education, and the Department for the Deaf and Hard-of-Hearing shall jointly disseminate the resource to parents of children from birth to age five who are deaf or hard of hearing.

E. The Department, in coordination with the Department of Education and the Department for the Deaf and Hard-of-Hearing, shall, after considering any recommendations submitted by the advisory committee, select existing tools or assessments for educators for use in assessing the language and literacy development of children from birth to age five who are deaf or hard of hearing. Such tools or assessments shall:

1. Be in a format that shows stages of language and literacy development;

2. Be selected for use by educators to track the expressive and receptive language acquisition and developmental stages toward English literacy of children from birth to age five who are deaf or hard of hearing; and

3. Be appropriate, in both content and administration, for use with children who are deaf or hard of hearing and who use American Sign Language, English, or both.

The Department, the Department of Education, and the Department for the Deaf and Hard-of-Hearing shall jointly disseminate the tools or assessments selected pursuant to this subsection to local educational agencies and provide materials and training on their use. Such tools or assessments may be used by a child's IFSP or IEP team, as applicable, to track the expressive and receptive language acquisition and developmental stages toward English literacy of such child or to establish or modify IFSP or IEP plans.

F. In addition to the powers and duties set forth above, the advisory committee may:

1. Advise the Department, the Department of Education, and the Department for the Deaf and Hard-of-Hearing or its contractor on the content and administration of the existing instrument used to assess the development of children who are deaf or hard of hearing in order to ensure the appropriate use of such instrument for the assessment of the language and literacy development of children from birth to age five who are deaf or hard of hearing; and

2. Make recommendations regarding future research to improve the measurement of the language and literacy development of children from birth to age five who are deaf or hard of hearing.

G. If a child from birth to age five who is deaf or hard of hearing does not demonstrate progress in expressive and receptive language skills as measured by one of the educator tools or assessments selected pursuant to subsection E or by the existing instrument used to assess the development of children who are deaf or hard of hearing, such child's IFSP or IEP team, as applicable, shall explain in detail the reasons why the child is not meeting or progressing toward the language developmental milestones and shall recommend specific strategies, services, and programs that shall be provided to assist the child's progress toward English literacy.

H. No later than August 1, 2020, and no later than August 1 of each year thereafter, the Department, in coordination with the Department of Education and the Department for the Deaf and Hard-of-Hearing, shall produce a report, using existing data reported in compliance with the federally required state performance plan on students with disabilities, that compares the language and literacy development of children from birth to age five who are deaf or hard of hearing with the language and literacy development of their peers who are not deaf or hard of hearing and shall make such report available to the public on its website.

I. The Department, the Department of Education, and the Department for the Deaf and Hard-of-Hearing shall comply with the provisions of the federal Individuals with Disabilities Education Act (20 U.S.C. § 1400 et seq.) and the Family Educational Rights and Privacy Act (20 U.S.C. § 1232g) in carrying out the provisions of this section.

Naloxone Public Storage and Access

SOURCE OF STUDY REQUEST:
House Joint Resolution 653 (chief patron: Delegate Wendy Gooditis, patron: Delegate Alfonso Lopez) requested that the Virginia Department of Health study the feasibility of expanding naloxone access through the placement of the drug in automated external defibrillator (AED) cabinets. The bill was heard in House Rules Subcommittee #1 where it was tabled with the understanding that the JCHC would receive a letter of request to conduct the study. During the discussion, the patron offered an amendment to broaden the scope of the study to include other public locations and the following letter of request from the patron includes this change.

SUMMARY OF REQUEST (Introduced resolution and letter from patron reflecting the changes (a) directing the study request to the JCHC and (b) the larger scope of the topic)**:**

House Joint Resolution 653 as introduced:
Whereas, the United States is experiencing a growing opioid epidemic, resulting in an alarming rise of opioid-related deaths; and

Whereas, naloxone is an antidote to opioid overdose, and timely administration of the drug can reverse opioid-induced respiratory depression; and

Whereas, naloxone is available in multiple dosage forms, including by nasal spray and injection; now, therefore, be it

resolved by the House of Delegates, the Senate concurring, that the Virginia Department of Health be requested to study the feasibility of expanding naloxone access through the placement of naloxone in automated external defibrillator (AED) cabinets across the Commonwealth.

In conducting its study, the Virginia Department of Health shall (i) determine any current barriers to expanding naloxone availability through its placement in AED cabinets; (ii) propose potential solutions, as practicable, to current barriers to expanding naloxone availability through its placement in AED cabinets; and (iii) develop and implement a program to educate schools, hospitals, public institutions, and the general public regarding current requirements for storage of and access to naloxone.

All agencies of the Commonwealth shall provide assistance to the Virginia Department of Health for this study, upon request.

Letter of request from patron:
I write to request a study from the Joint Commission on Health Care in 2019 concerning public access to naloxone, a life-saving drug that reverses the effects of opioid overdoses… To best serve the needs of the public, I would request this study examine:

- whether removing barriers to administering Naloxone, such as the requirement to obtain training before using the drug, is likely to save lives without causing significant damage to public health, and
- if so, which barriers to administration we should remove, and
- whether and how we could place naloxone in publicly accessible places, such as alongside Automatic Electronic Defibrillators (AEDs)

HAS TOPIC BEEN STUDIED FOR VIRGINIA GOVERNMENT, OR IN OTHER STATES, IN THE LAST 10 YEARS?

YES _____ NO __X__.

ADDITIONAL INFORMATION:

Naloxone, when given during or immediately after an opioid overdose, can reverse the negative, often fatal, effects of the drug. As a result, States have taken a variety of steps in recent years to increase availability of naloxone.[11] These include provider standing orders that permit pharmacists to issue non-patient prescriptions and the distribution of naloxone in community settings by lay individuals who have undergone special training. With the availability of easier-to-use forms of dispensing (i.e. a nasal spray and pre-filled auto injector) there has been greater consideration of more diverse ways to distribute the drug in a community. While no states provide for storage of naloxone in AED cabinets, pilot programs have recently emerged, including placement of naloxone in AED cabinets in buildings associated with the Department of Veteran's Affairs and in Delaware County, Pennsylvania. Additionally, some universities co-locate naloxone in AED cabinets.

During follow-up conversations, Delegate Gooditis indicated that she would like the study to focus on public locations that are staffed (as opposed to other public locations, such as parks) and broader channels for public distribution of naloxone (e.g., community-based distribution).

DRAFT WORK PLAN FOR STUDY:

- Collect Virginia data on:
    - AED location information (data sources TBD)
    - Other potential public locations for naloxone placement
    - Opioid overdoses (OCME and ODMAP via the Washington / Baltimore HIDTA)
        - Number of overdoses per year
        - Location of overdoses to guide whether, and if so where, to publicly place naloxone
        - Percent of overdoses that were fatal/not fatal by naloxone use
    - Naloxone costs (nasal spray, auto-injectors, etc.) and potential funding sources
- Review literature on:
    - Overdoses and administration of naloxone
    - Training standards of naloxone administration
    - Experiences of pilot programs of AED-naloxone co-location, location in publicly accessible places, and community-based distribution of naloxone
    - Potential problems/concerns regarding public placement of naloxone and possible solutions/alternatives
- Determine Code of Virginia changes required to address: 1) co-location of naloxone with AEDs as well as other public areas of access; 2) lay administration with lesser levels of training than currently required
- Determine level of interest in, and concerns with, potential public locations for naloxone (e.g., libraries)
    - Determine staff training options, the cost of staff training, and funding sources, (including state GFs, donations, etc.)

[11] Preventing the Consequences of Opioid Overdose: Understanding Naloxone Access Laws (https://www.samhsa.gov/capt/sites/default/files/resources/naloxone-access-laws-tool.pdf)

- Determine the need for, and requirements of, developing a program to educate public institutions, other institutions as appropriate (e.g., hospitals) and the general public regarding naloxone storage, access and administration

Stakeholders to contact:

- Attorney General's Office
- Board of Pharmacy
- Department of Behavioral Health & Developmental Services
- Department of Education
- Law enforcement (Sheriff's Association; State Police Association; Police Chief's Association)
- Naloxone manufacturers
- Representatives of public locations
- Virginia Association of School Boards
- Virginia Department of Health
- Virginia Hospital & Healthcare Association
- Virginia Pharmacists Association
- Virginia Trial Lawyers Association

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): Medium

Increased Prescription Delivery Options at Same Cost for Health Plan Members

SOURCE OF STUDY REQUEST:
The JCHC Chair received a letter indicating that the Senate Committee on Education and Health referred the subject matter contained in House Bill 2223 (Delegate O'Quinn) to the Joint Commission on Health Care for study with the request that a report be submitted to the Chair of the Education and Health Committee, the bill patrons, and the Office of the Senate Clerk by November 1, 2019.

SUMMARY (as passed the House; see section "HB 2223 AS PASSED THE HOUSE – TEXT" of SIF for full text of bill):
HB 2223 requires every health carrier, as applicable, to administer its health benefit plans in a manner consistent with, or include in contracts for pharmacy benefits management, criteria and provisions that:

- Permit a covered individual to fill any mail order-covered prescription, at the covered individual's option, at any mail order pharmacy or network participating retail community pharmacy if the network participating retail community pharmacy agrees to accept a price that is comparable to that of the mail order pharmacy, calculated to reflect all drug manufacturer's rebates, direct and indirect administrative fees, costs and any remuneration;
- Prohibit a pharmacy benefits manager (PBM) or carrier from imposing a differential copayment, additional fee, or other condition on any covered individual who elects to fill his prescription at an in-network retail community pharmacy that is not similarly imposed on covered individuals electing to fill a prescription from a mail order pharmacy; and
- Require the PBM to use the same benchmark index to reimburse all pharmacies participating in the health benefit plan regardless of whether a pharmacy is a mail order pharmacy or a retail community pharmacy.

The measure applies with respect to contracts entered into, amended, extended, or renewed on or after January 1, 2020.

HAS TOPIC BEEN STUDIED FOR VIRGINIA GOVERNMENT, OR IN OTHER STATES, IN THE LAST 10 YEARS?
YES _____ NO __X__.

A workgroup convened by the Department of Health Professions (DHP) in 2016 examined issues relating to state oversight of PBMs. However, overlap in the scope of DHP workgroup activities and this study is limited. Issues examined and policy options considered by the DHP workgroup related to electronic prior authorization, modes of delivery of prescriptions from specialty pharmacies, defining criteria for specialty drugs, and increasing the Commonwealth's ability to oversee PBM activities.[12]

ADDITIONAL INFORMATION:
HB 2223's Fiscal Impact Statement noted an "indeterminate" impact on the Department of Human Resources Management (DHRM) (Item 8) and that aspects of SB 2223 may conflict with both federal rules and existing Virginia Statute (Item 11).[13]

There are examples of other states pursuing similar approaches to requirements described in HB 2223. Kansas considered (but did not pass) legislation in 2014 (HB 2688) containing language nearly identical

[12] Department of Health Professions, 2016. "Report of the Pharmacy Benefit Managers Workgroup." https://virginiapharmacists.org/wp-content/uploads/2016/06/DHP_Report_on_Pharmacy_Benef.pdf
[13] The Fiscal Impact Statement is included in the section "HB 2223-H1 FISCAL IMPACT STATEMENT"

to that in HB 2223 B(1) and B(2).[14] New York passed legislation in 2011 (A05502) with requirements similar in intent to those same sections of HB 2223.

More generally, while U.S. States have considered several options to control pharmaceutical costs to consumers through regulation of Pharmacy Benefit Managers (PBMs), legislation considered typically has not focused on price differentials between mail order and retail pharmacies. Examples of approaches taken or considered both by other states and in Virginia include: greater transparency on price spreads, banning the use of PBM "gag" clauses that prohibit pharmacies from disclosing less costly alternatives, allowing pharmacies to disclose state oversight of PBMs through licensure and registration, and establishing rules for PBM pharmacy audits.

In Virginia, the pharmacy-related "Freedom of Choice" Act (§§38.2-4209.1, 38.2-3407.7, 38.2-4312.1,), prohibits insurers, health plans and HMOs regulated by the state from imposing limitations on beneficiaries from filling prescriptions at pharmacies of their choice, including non-preferred providers. Several requirements of the Act are designed to ensure that patients do not pay more for services received from non-preferred providers compared to preferred providers. However, provisions of the Act do not apply to mail order pharmacies that are selected by an insurer, health plan or HMO as its exclusive provider of pharmacy services.

DRAFT WORK PLAN FOR STUDY:

- Review literature on states' approaches to containing prescription costs faced by consumers from mail order and community retail pharmacies, with a focus on policies related to PBMs.
- Collect data, if available, on volume of pharmacy sales from community retail and mail order pharmacies (source: Department of Taxation)
- Determine further refinements to HB 2223 that may be warranted:
    - Under HB 2223 section B(1): how would "comparable" prices be determined? Are there appropriate enforcement mechanisms for PBMs found to be out of compliance with HB 2223's requirements?
    - Address other concerns raised in the Fiscal Impact Statement (For example, section 11 lists three issues that need to be addressed if the bill is to be introduced in an upcoming session.)

Stakeholders to contact:

- Board of Pharmacy
- Department of Human Resources Management
- State Corporation Commission Bureau of Insurance
- Consumer Health Products Association
- PhRMA
- Virginia Association of Health Plans
- Virginia Pharmacists Association

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): Medium-high

[14] HB 2223 subsection B(1) relates to covering prescriptions at network participating non-mail order retail pharmacy at comparable prices to mail order options; subsection B(2) prohibits differential copayment.

HB 2223 AS PASSED THE HOUSE – TEXT

HOUSE BILL NO. 2223

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Commerce and Labor
on January 31, 2019)

(Patron Prior to Substitute--Delegate O'Quinn)

*A BILL to amend the Code of Virginia by adding a section numbered **38.2-3407.15:5**, relating to pharmacy services; mail order and delivery; pharmacy benefits managers.*

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered **38.2-3407.15:5** as follows:

*§ **38.2-3407.15:5**. Access to retail community pharmacies.*

A. As used in this section:

*"Carrier" has the same meaning ascribed thereto in subsection A of § **38.2-3407.15**.*

"Covered individual" means an individual receiving prescription medication coverage or reimbursement provided by a pharmacy benefit manager or a carrier under a health benefit plan.

*"Health benefit plan" has the same meaning ascribed thereto in § **38.2-3438**.*

"Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail or through electronic submissions and to dispense medication to covered individuals through the use of the United States mail or other common or contract carrier services and provides any consultation with covered individuals electronically rather than face-to-face.

"Pharmacy benefits manager" or "PBM" means a person that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a carrier, nonprofit hospital, or third-party payor under a health program administered by the Commonwealth.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of covered individuals.

"Retail community pharmacy" means a pharmacy that is open to the public, serves walk-in customers, and makes available face-to-face consultations between licensed pharmacists and persons to whom medications are dispensed.

B. Every carrier shall, as applicable, (i) administer its health benefit plans in a manner consistent with the following criteria and (ii) include the following provisions in each provider contract addressing the provision of pharmacy benefits management that the carrier or the carrier's pharmacy benefits manager enters into with a pharmacy or the pharmacy's contracting agent:

1. Each covered individual shall be permitted to fill any mail order-covered prescription, at the covered individual's option, at any mail order pharmacy or network participating retail community pharmacy if the network participating retail community pharmacy agrees to accept a price that is comparable to that of the mail order pharmacy, calculated to reflect all drug manufacturer's rebates, direct and indirect administrative fees, costs and any remuneration;

2. The PBM or carrier shall not impose a differential copayment, additional fee, or other condition on any covered individual who elects to fill his prescription at an in-network retail community pharmacy that is not similarly imposed on covered individuals electing to fill a prescription from a mail order pharmacy; and

3. The PBM shall utilize the same benchmark index, including the same average wholesale price, maximum allowable cost, and national prescription drug codes, to reimburse all pharmacies participating in the health benefit plan regardless of whether a pharmacy is a mail order pharmacy or a retail community pharmacy.

C. This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974, Medicaid, or Medicare Part D.

D. This section shall apply with respect to contracts with a PBM entered into, amended, extended, or renewed on or after January 1, 2020.

*E. Pursuant to the authority granted by § **38.2-223**, the Commission may promulgate such rules and regulations as it may deem necessary to implement this section.*

F. The Commission shall have no jurisdiction to adjudicate individual controversies arising out of this section.

HB 2223-H1 FISCAL IMPACT STATEMENT

Department of Planning and Budget
2019 Fiscal Impact Statement

1. **Bill Number:** HB2223-H1

House of Origin	☐	Introduced	☒	Substitute	☐ Engrossed
Second House	☐	In Committee	☐	Substitute	☐ Enrolled

2. **Patron:** O'Quinn

3. **Committee:** Commerce and Labor

4. **Title:** Pharmacies; delivery of prescription drugs; pharmacy benefits managers.

5. **Summary:** Requires health carriers to administer its health benefit plans in a manner consistent with, and include in contracts for pharmacy benefits management, criteria and provisions that (i) permit a covered individual to fill any mail order-covered prescription, at the covered individual's option, at any mail order pharmacy or network participating retail community pharmacy if the network participating retail community pharmacy agrees to accept a price that is comparable to that of the mail order pharmacy, calculated to reflect all drug manufacturer's rebates, direct and indirect administrative fees, costs and any remuneration; (ii) prohibit a pharmacy benefits manager (PBM) or carrier from imposing a differential copayment, additional fee, or other condition on any covered individual who elects to fill his prescription at an in-network retail community pharmacy that is not similarly imposed on covered individuals electing to fill a prescription from a mail order pharmacy; and (iii) require the PBM to use the same benchmark index to reimburse all pharmacies participating in the health benefit plan regardless of whether a pharmacy is a mail order pharmacy or a retail community pharmacy. The measure applies with respect to contracts entered into, amended, extended, or renewed on or after January 1, 2020.

6. **Budget Amendment Necessary**: No.

7. **Fiscal Impact Estimates:** Fiscal impact is indeterminate; see Item 8.

8. **Fiscal Implications:** There is no fiscal impact for the State Corporation Commission or the Department of Health Professions. However, according to the Department of Human Resource Management (DHRM), the fiscal impact to the state employee health plan is indeterminate.

   Department of Human Resource Management:

   The bill provides that a covered individual may fill a mail-order covered prescription at any mail order pharmacy or network participating retail pharmacy if the retail pharmacy accepts a price that is comparable to that of the mail order pharmacy. The bill also requires the pharmacy benefits manager to "utilize the same benchmark index, including the same average wholesale price, maximum allowable cost, and national prescription drug codes, to reimburse all pharmacies participating in the health benefit plan regardless of whether a

pharmacy is a mail order pharmacy or a retail community pharmacy." It is unknown how these requirements may affect the cost of prescriptions for the state employee health plan. The bill provides that requirements shall apply to contracts with a pharmacy benefits manager entered into, amended, extended, or renewed on or after January 1, 2020.

The bill also provides that differential copayments shall not be imposed on individuals electing to fill a prescription at an in-network retail pharmacy that are not similarly imposed on those electing to fill a prescription from a mail order pharmacy. According to DHRM, members in COVA Care, the largest state employee health insurance option, currently pay a lower copay for a 90 day supply of prescription drugs purchased through mail order than at participating retail pharmacies.

The fiscal impact on state health insurance premiums cannot be determined and would depend on the cost of prescriptions negotiated pursuant to the requirements of the bill and prescription copayment levels that are imposed similarly for mail order and retail prescription delivery methods, as required by the bill.

9. **Specific Agency or Political Subdivisions Affected:** State Corporation Commission Bureau of Insurance, Department of Health Professions, and Department of Human Resource Management.

10. **Technical Amendment Necessary:** See Item 11.

11. **Other Comments:** The State Corporation Commission Bureau of Insurance notes that federal rules at 45 CFR 156.122 indicate that there may be instances in which certain prescriptions will not be available at a retail pharmacy: (i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or (ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. The bill does not contemplate the provision for these exceptions.

    Proposed B 1 of Section 38.2-3407.15:5 of House Bill 2223 creates a conflict with the pharmacy freedom of choice provisions in Subsections 38.2-3407.7 F, 38.2-4209.1 F and 38.2-4312.1 F which allow a carrier to select a single mail order pharmacy provider as the exclusive provider of pharmacy services and not be subject to pharmacy freedom of choice provisions. This would render those subsections invalid because subsection B 1 allows a covered individual to fill any mail-order covered prescription at any mail order pharmacy.

    Subsection C will render this bill not applicable to most fully-insured employer plans. The Bureau of Insurance notes that employer plans can be ERISA plans and still be fully-insured. The Bureau advises that if the bill was not intended to apply to self-insured plans, the definition of "health benefit plan" should only mention the exclusion of Medicaid and Medicare Part D, not the Employee Retirement Income Security Act of 1974.

Supported Decision-Making for Individuals with Intellectual and Developmental Disabilities

SOURCE OF STUDY REQUEST: House Joint Resolution 729 (Delegate Kaye Kory) requested the Secretary of Health and Human Resources to study supported decision-making for individuals with intellectual and developmental disabilities. However, House Rules Committee tabled the resolution with the understanding that the JCHC would receive a letter of request to conduct the study.

SUMMARY (Provided in Resolution or Letter of Request):
Whereas, supported decision-making is a process through which individuals with intellectual and developmental disabilities receive assistance in making and communicating important life decisions; and

Whereas, many individuals with intellectual and developmental disabilities in the Commonwealth have not been provided opportunities for supported decision-making with regard to important life decisions, including health care decisions and options; and

Whereas, it is important that individuals with intellectual and developmental disabilities in the Commonwealth have the opportunity to make supported, informed choices about important life decisions; and

Whereas, a comprehensive study of supported decision-making in the Commonwealth may improve the personal autonomy and quality of life of individuals with intellectual and developmental disabilities and help ensure that they receive assistance in making and communicating important life decisions; now, therefore, be it

Resolved by the House of Delegates, the Senate concurring, that the Secretary of Health and Human Resources be requested to study supported decision-making for individuals with intellectual and developmental disabilities.

In conducting this study, the Secretary of Health and Human resources shall (i) examine the use of supported decision-making for individuals with intellectual and developmental disabilities in the Commonwealth; (ii) compare the Commonwealth's policies and practices related to supported decision-making and informed choice to the policies and practices used in other states; (iii) examine situations in which the use of supported decision-making is an appropriate alternative to the appointment of a guardian; (iv) after consultation with the Arc of Virginia, Voices of Virginia, the Autism Society, the disAbility Law Center of Virginia, the Down Syndrome Association, the Jenny Hatch Justice Project, the Virginia Bar Association, the Virginia Department of Behavioral Health and Developmental Services, and the Office of the Executive Secretary of the Supreme Court of Virginia, (a) recommend strategies to improve the use of supported decision-making in the Commonwealth and ensure that individuals with intellectual and developmental disabilities are consistently informed and receive the opportunity to participate in their important life decisions and (b) determine whether legislation related to supported decision-making is necessary and, if so, propose specific legislative recommendations.

All agencies of the Commonwealth shall provide assistance to the Secretary of Health and Human Resources for this study, upon request.

The Secretary of Health and Human Resources shall complete his meetings by November 30, 2019, and shall submit to the Governor and the General Assembly an executive summary and a report of his findings and recommendations for publication as a House or Senate document. The executive summary

and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports no later than the first day of the 2020 Regular Session of the General Assembly and shall be posted on the General Assembly's website.

HAS TOPIC BEEN STUDIED IN THE POLICY ARENA IN VIRGINIA, OR IN OTHER STATES, IN THE LAST 10 YEARS?

YES _X_ NO ____.

ADDITIONAL INFORMATION:

In Virginia, SDM rose to public consciousness in 2013 with the court case of Margaret "Jenny" Hatch. In that case, the Circuit Court of Newport News rejected Jenny Hatch's parents' petition for guardianship. Conversely, it held that she should be placed in a one-year limited guardianship (with two guardians that were Jenny Hatch's preference), with the goal to transition to a SDM model, including the use of SDM during guardianship.

On March 4, 2014 HJR 190 was enacted which requested that the Secretary of Health and Human Resources study supported decision-making for individuals with intellectual and developmental disabilities. The language in HJR 190 was very similar to the language in HJR 729. HJR 190 resulted in House Document No. 6, Supportive Decision-Making Study, published in 2015. The study reported that the Commonwealth had no defined policies or practices related to supported decision-making and could not find any in other states. The report noted that many states were exploring the policy and one was conducting research on it within the disability community to determine how it might work.

The report listed four initial recommendations

- Begin to formalize supported decision-making as a legitimate alternative to guardianship and conservatorship statute as well as to DBHDS code concerning Authorized Representatives.
- Require individuals appointed to positions of guardians or authorized representatives to receive designated training.
- Develop a standardized procedure for completing capacity evaluations.
- General training on capacity and supported decision making be developed and offered that includes a discussion of all types of decision making assistance commonly used and type of clinical presentation is appropriate for each.

In addition to House Document No. 6, a number of resources are available that provide information on supported decision-making, and other states have addressed this issue since the 2014 report. For example, in 2017 the Council on Quality and Leadership published a white paper on supported decision making in the United States and profiled 11 states (Texas, Delaware, Indiana, Maine, Massachusetts, Maryland, Michigan, New York, North Carolina, Virginia and Wisconsin). According to the white paper, Texas and Delaware were the first states to pass legislation related to supported-decision-making, Texas in 2015 and Delaware in 2016. Finally, the white paper notes the difficulties of balancing between "concerns of safety and supervision versus allowing individuals to maintain control over their own decision-making and their own legal capacity."

DRAFT WORK PLAN FOR STUDY:

- Per the resolution, contact the Arc of Virginia, Voices of Virginia, the Autism Society, the disABILITY Law Center of Virginia, the Down Syndrome Association, the Jenny Hatch Justice Project, the Virginia Bar Association, the Virginia Department of Behavioral Health and Developmental Services, and the Office of the Executive Secretary of the Supreme Court of Virginia
- Contact the Virginia Department of Social Services; Virginia Department of Medical Assistance Services; Virginia Department of Education; Jonathan Martinis, Director for Law and Policy with the Burton Blatt Institute; Sharon and Conner Cummings, Autism Advocates in Virginia; and Marisa Brown, RN, Disability Rights International
- Review recommendations from the Virginia report published in 2015, HD 6; provide any available updates for Virginia, and determine what the states mentioned in the report (Pennsylvania, Massachusetts, North Carolina and Maryland) have done since 2014
- Review literature, studies and any available data on SDM. Literature review will include state and federal laws
- Contact agency officials in states where similar legislation has been introduced, passed or failed to obtain information and/or data that may aid Virginia legislators in their decision-making process regarding this issue.
- Review federal laws and regulations regarding the use of supported decision-making.

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): Medium to high

Forensic Nursing in the Commonwealth

SOURCE OF STUDY REQUEST:

House Joint Resolution 614; introduced by Delegate Karrie Delaney (chief patron), and Delegates Dawn Adams, Betsy Carr, Kelly Convirs-Fowler, James Edmunds II, Kaye Kory, Joseph Lindsey, Sam Rasoul, David Reid, Debra Rodman, Danica Roem, Mark Sickles, Marcus Simon, Rip Sullivan Jr, Roslyn Tyler and Senator Jennifer McClellan (patrons); directed the Virginia State Crime Commission to study forensic nursing in the Commonwealth. Based on the likelihood of a heavy workload, the Crime Commission Director requested the JCHC to conduct the study if the members of both commissions concur.

SUMMARY OF RESOLUTION:

In conducting its study, the Virginia State Crime Commission (the Commission) shall (i) identify all existing forensic nursing programs in the Commonwealth, including graduate programs and certifications; (ii) determine geographic regions of the Commonwealth in which forensic nursing programs or forensic nurses do not currently exist and determine what coverage is available in those regions, if any, and whether coverage is provided from neighboring regions; (iii) identify the current funding sources for existing forensic nursing programs and estimate the costs associated with and potential funding sources for establishing forensic nursing programs in five geographic regions across the Commonwealth with a current gap in coverage; (iv) analyze and provide an estimate of the average costs associated with collecting forensic evidence and providing testimony in a court of law and identify funding sources for testimony costs; (v) review the current forensic nursing workforce in the Commonwealth and identify opportunities to increase availability of forensic nursing certifications to nurses; (vi) consider insurance reimbursement opportunities for forensic nursing services performed; and (vii) evaluate existing forensic nursing programs in other states and identify best practices, including telehealth, that could be utilized in the Commonwealth.

HAS TOPIC BEEN STUDIED IN THE POLICY ARENA IN VIRGINIA, OR IN OTHER STATES, IN THE LAST 10 YEARS?

YES __X__ NO__ .

ADDITIONAL INFORMATION:

Background

Only 32.5% of rape or other sexual assault incidents were reported to law enforcement in 2015, according to the US Department of justice.[i] One of the barriers to reporting may be a lack of timely access to properly trained and certified forensic nurses and examiners. The specialty of forensic nurse examiner is a cross between the healthcare and judicial system professions. Forensic nurses collect evidence for law enforcement officers and give testimony in a court of law during prosecutions. According to *nursingschool.org*, the largest subspecialty of forensic nursing is sexual assault, closely followed by death investigation, forensic psychiatric nursing and medical-legal consulting. To become a forensic nurse a registered nurse, or nursing student, must take specific classes, or continuing education, and may become certified as a Sexual Assault Nurse Examiner-Adult/Adolescent (SANE-A) or Sexual Assault Nurse Examiner-Pediatric (SANE-P).[ii]

While sexual assault forensic exams may be performed by any medical professional, the exams are intrusive and can be physically and emotionally difficult for the victim in a time of trauma. Forensic nurses are trained specifically to administer the exams, provide trauma-informed care to victims for the benefit of their mental and physical health, and to properly collect evidence. A Colorado study found

that evidence collection kits prepared by forensic nurses were more accurate and complete than evidence collection kits prepared by untrained nurses and physicians.[iii] Another study found that clinical care and treatment of victims of rape and sexual assault was "significantly better" when the forensic exams were performed by forensic nurses.[iv] However, according to the President of the International Association of Forensic Nurses, there are only 63 certified sexual assault forensic nurses in Virginia out of 93,902 licensed Registered Nurses practicing in the state.[v]

Examples of Recent Reports and Studies

The Virginia Department of Forensic Science (DFS) formed a Physical Evidence Recovery Kit (PERK) Work Group in 2015. [vi] The PERK Work Group formed four subcommittees to review: Data Bank/Testing Issues, Law Enforcement/Submission Issues, Victim Consent/Notification Issues, and Hospital/Collection Issues; and held three meetings in the fall of 2015. Fourteen recommendations were adopted to improve PERK collection procedures, analysis, testing and storage. Recommendations one through 13 led to the passage of SB 291 (2016) and regulatory changes by DFS.[vii] Recommendation 14 was not addressed. It stated:

> Convene a DFS stakeholder group to study: the creation of a "Preservation of Biological Evidence" Task Force to meet annually, the reimbursement for forensic exams and forensic science services (including testimony), standard of care for victims of sexual assault and oversight for forensic nursing programs, criteria for when a PERK should be collected from a sexual assault victim who is a minor, resources available for forensic nursing programs and the appropriate allocation of resources to provide for the needs of sexual assault victims across the state, including grant opportunities for forensic nursing programs and training needs.

In 2016, the GAO did an in depth study of Sexual Assault Nurse Examiner (SANE) coverage in six states: Massachusetts, Oregon, Wisconsin, Colorado, Florida, and Nebraska. In every state, the need for nurse examiners was far higher than the supply. Four out of six states had only "few or some" hospitals with SANE care available. The GAO also reviewed three federal grant programs that either set aside funds for examiner training or allowed funds to be used for examiner training. Virginia received grant funds from two of the programs, the Services-Training-Officers-Prosecutors Violence Against Women Formula Grant Program (STOP Grant Program) and the Grants to Encourage Arrest Policies and Enforcement of Protection Orders Program (Arrest Grant Program).[viii] In 2013, seven grantees in Virginia reported training 157 forensic examiners under the STOP program and three grantees reported training 10 examiners in 2014 under the Arrest Grant program. The GAO noted that their audit could not determine how many examiners received comprehensive training versus any other type of training that could be used to enhance their abilities to serve victims.[ix, x]

In 2014, Maryland established a "Planning Committee to Implement Improved Access to Sexual Assault Medical Forensic Examinations." The committee met for a year and issued a report to the Governor with findings and recommendations aimed at improving access to "sexual assault medical forensic examinations" (SAFEs).[xi] The report found that there was a burden on victims who present for treatment at hospitals that do not have a SAFE program (e.g. delayed care and possible loss of evidence due to transportation – often not covered by insurance - to another hospital, and a lack of protocols for the process). The report also indicated that other states had some success with (a) comprehensive centers with forensic nurses trained to assist multiple types of victims, (b) Mobile SAFE units by which a forensic nurse can travel to victims and perform an exam, and (c) telemedicine technology to increase access to forensic providers in remote areas.[xii]

There were many recommendations from the Maryland report including: increased provider reimbursements, reimbursements for mobile forensic nurse examiners, increased public education and awareness about the location and accessibility of SAFE programs, and how to contact local sexual assault crisis programs.[xiii]

DRAFT WORK PLAN FOR STUDY:

- Review current state and federal laws, including laws from other states, related to the study request (i.e. forensic nurse requirements, training opportunities, reimbursement issues, etc.).
- Review and provide information on the implementation of the provisions in SB 291 relevant to the current study; and determine whether funding provided to DFS is still available.
- Contact Maryland officials to discuss their report and any updates on the findings and recommendations.
- Review other state and health policy organization resources regarding best practices.
- Tour some of the Virginia forensic nursing programs.
- Meet with stakeholders involved with forensic nursing, including Kelly Canon, from Virginia Hospital and Healthcare Association, and Sara B. Jennings and Bonnie Price with Bon Secour's Forensic Department, who are leaders in promoting forensic nursing in Virginia and nationally.
- Solicit input from the following:
    - Virginia Department of Forensic Science, the Department of Criminal Justice Services, and the Office of Chief Medical Examiner
    - Virginia Department of Health Professions and the Virginia Board of Nursing
    - International Association of Forensic Nurses – Certification Center
    - Office of the Attorney General, prosecutors and other legal experts
    - Law enforcement officials
    - Victims Compensation Fund
    - Various forensic nursing programs: VCU, Liberty University, Southside Virginia Community College, Hampton University, Tidewater Community College, Stratford University, Northern Virginia Community College, Marymount University, ECPI University
    - American Nurses Credentialing Association
    - US Department of Justice Office of Violence Against Women
    - Virginia Victim Assistance Network

ESTIMATED WORKLOAD REQUIREMENT (based on proposed study work plan): High

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[i] Morgan, Rachel E. PhD. and Grace, Kena. Criminal Victimization, 2016: Revised. U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics. October 2018.

[ii] Price, Bonnie, DNP, RN, SANE-A, SANE-P, AFN-BC; Administrative Director Community Health Advocacy. Bon Secours Richmond Health System. "RE: #ExtMail# Unedited Background from Conversation Yesterday". Email to Stephen Weiss. April 10, 2019.

[iii] Sievers, V. et. al. Sexual assault evidence collection more accurate when completed by sexual assault nurse examiners: Colorado's experience. Abstract, Journal Emergency Nursing. December 29, 2003.

[iv] Chukwudozie, Ada and White, Howard White. Forensic Nurse Examiners versus Doctors for the Forensic Examination of Rape and Sexual Assault Complaints. The Campbell Collaboration, Systematic Review. 2014.

[v] Jennings, Sara, DNP, RN, SANE-A, SANE-P, AFN-BC, President-elect of the International Association of Forensic Nurses and Manager, and Price, Bonnie, DNP, RN, SANE-A, SANE-P, AFN-BC. Administrative Director, Community Advocacy, Bon Secours Richmond Forensic Nursing Services. "FW: #ExtMail# RE: testimony of Sara Jennings." Emails to Stephen Weiss. 5:58 p.m. April 8 and 10, 2019; and Virginia's Registered Nurse Workforce: 2018. Virginia Department of Health Professions, October 2018. page 4.

[vi] The Work Group was formed by Governor Terry McAuliffe after DFS submitted a PERK Inventory Report to the General Assembly, as required by Senate Bill 568 (Chapter 642 of the 2014 Acts of Assembly). Senate Bill 658 (2014) directed "[a]ll local and state law-enforcement agencies [to] report an inventory of all physical evidence recovery kits in their custody that may contain biological evidence that were collected but not submitted to the Department of Forensic Science for analysis prior to July 1, 2014" and that DFS report the results of such inventory to the General Assembly on or before July 1, 2015.

[vii] https://www.dfs.virginia.gov/wp-content/uploads/2016/07/Perk-Work-Group-Report.pdf

[viii] The 3rd grant program, Rural Sexual Assault Domestic Violence, Dating Violence, and Stalking Assistance Program (Rural Grant Program) was designated for rural states based on population density; Virginia did not qualify.

[ix] United States Government Accountability Office. Sexual Assault Information on Training, Funding, and the Availability of Forensic Examiners. March 2016. page 10, 14, 34 and 36.

[x] GAO notes indicate that training data is collected by each grant and there may be a duplication in the counts between the grants.

[xi] Maryland House Bill 963 (Chapter 627, Section 2(g) of the Acts of 2014)

[xii] Mitchell, Van, Secretary of the Maryland Department of Health and Mental Hygiene and Seaman, Kevin, Executive Director, Maryland Institute for Emergency Medical Services Systems. Report on the Improved Access to Sexual Assault Medical Forensic Examinations in Maryland-House Bill 963/Chapter 627, Section 2(g) of the Acts of 2014. December 1, 2015. Pages 3.

[xiii] Ibid. (Mitchell) Pages 3 - 7.