Virginia Department of Health Professions
Board of Medicine

Welcome to the Advisory Board on Physician Assistants

The Virginia Board of Medicine will hold an electronic meeting of the Advisory Board on Physician Assistants on **January 28, 2021 at 1:00 P.M.** This meeting will be supported by Cisco WebEx Meetings application.

For the best WebEx experience, you may wish to download the Cisco WebEx Meeting application on your mobile device, tablet or laptop in advance of the meeting. Please note that WebEx will make an audio recording of the meeting for posting

This electronic meeting is deemed warranted under Amendment 28 to HB29 based on that requiring in-person attendance by the Advisory Board members is impracticable or unsafe to assemble in a single location.

Comments will be received from those persons who have submitted an email to william.harp@dhp.virginia.gov no later than 8:00 a.m. on January 27, 2021 indicating that they wish to offer comment. Comment may be offered by these individuals when their names are announced by the chairman.

Whether you are a member of the Advisory Board or a member of the public, you can join the meeting in the following ways.

- **JOIN by WEBEX**

https://covaconf.webex.com/covaconf/j.php?MTID=m130780bef41cfb6eaa50416ef63b7f82
Meeting number (access code): 178 269 0242

- **JOIN BY PHONE**

+1-517-466-2023 US Toll
+1-866-692-4530 US Toll Free
Meeting number (access code): 178 269 0242

TECHNICAL DIFFICULTIES: Should you experience technical difficulties, you may call the following number: (804) 339-0627 for assistance. Any interruption in the telephonic or video broadcast of the meeting shall result in the suspension of action at the meeting until repairs are made and public access is restored.

The Board of Medicine and the Freedom of Information Act Council are interested in your evaluation of the electronic experience of this meeting. You can provide comment via the following form **HERE**.

Advisory Board on Physician Assistants

Board of Medicine

Thursday, January 28, 2021 @ 1:00 p.m.

9960 Mayland Drive, Suite 300, Henrico, VA

Electronic Meeting

DRAFT UNAPPROVED

ADVISORY BOARD ON PHYSICIAN ASSISTANTS
Minutes
October 8, 2020
Electronic Meeting

The Advisory Board on Physician Assistants held a virtual meeting on Thursday, October 8, 2020 hosted at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Henrico, Virginia.

MEMBERS PRESENT:	Portia Tomlinson, PA-C, Chair Kathleen Scarbalis, PA-C Frazier W. Frantz, MD James Carr, PA-C Tracey Dunn, Citizen
MEMBERS ABSENT:	None
STAFF PRESENT:	William L. Harp, MD, Executive Director Michael Sobowale, LLM., Deputy Director, Licensing Colanthia Morton Opher, Deputy Director, Administration Elaine Yeatts, DHP Senior Policy Analyst Yetty Shobo, PhD, Healthcare Workforce Data Center ShaRon Clanton, Licensing Specialist
GUESTS PRESENT:	Jonathan Williams, VAPA Scott Johnson, JD, MSV Robert Glasgow, PA-C, VAPA

Call to Order

Ms. Tomlinson called the meeting to order at 10:17 am.

Emergency Egress Procedures

Dr. Harp announced the emergency egress instructions.

Roll Call

DRAFT UNAPPROVED

Roll was called; all advisory board members present. A quorum was established.

Approval of Minutes May 23, 2019

Ms. Scarbalis moved to adopt the minutes. The motion was seconded by Ms. Dunn. By roll call vote, the minutes were approved as presented.

Adoption of Agenda

Ms. Scarbalis moved to adopt the agenda with the topic of the physician assistant licensure compact added to the agenda. The motion was seconded by Mr. Carr. By roll call vote, the adoption of the agenda as amended carried unanimously.

Public Comment on Agenda Items (15 minutes)

None

Healthcare Workforce Data Presentation

Yetty Shobo, PhD, presented the workforce data for physician assistants surveyed in 2019. Her presentation showed a younger workforce and stable economic prospects for the profession as part of their findings.

NEW BUSINESS

1. Proposed Regulations for Public Hearing

   Ms. Tomlinson conducted a Public Hearing to receive comment on proposed amendments relating to the replacement of emergency regulations with final regulations on physician assistant collaborative practice with a patient care team physician. There was no public comment. Ms. Tomlinson concluded the hearing.

2. Physician Assistant Licensure Compact

   Ms. Scarbalis gave a report on the meeting organized by the Federation of State Medical Boards on November 21st, 2019 in Washington, DC at which the physician assistant licensure compact was discussed.

   This report was for information only, and no action was required.

DRAFT UNAPPROVED

3. Report of Regulatory Actions and 2020 General Assembly

   Mrs. Yeatts provided a legislative update and report of the 2020 General Assembly. She discussed bills that were of interest to members.

4. Approval of 2021 Meeting Calendar

   Ms. Tomlinson moved to approve the 2021 proposed meeting dates for the Advisory Board as presented. The motion was seconded by Ms. Scarbalis. By roll call vote, the schedule of meetings for 2021 was approved.

5. Election of Officers

   Ms. Tomlinson nominated Kathleen Scarbalis for Chair. James Carr seconded. Ms. Tomlinson nominated Mr. Carr for Vice-Chair. Ms. Dunn seconded. By roll call vote, Kathleen Scarbalis was approved as Chair, and James Carr was approved as Vice-Chair.

Announcements

Next Scheduled Meeting: January 28, 2021 @ 1:00 p.m.

Adjournment

With no other business to conduct, the meeting adjourned at 2:11 p.m.

Portia Tomlinson, PA-C, Chair

William L. Harp, MD, Executive Director

ShaRon Clanton, Licensing Specialist

Report of the 2021 General Assembly Session

January 20, 2021

HB 1737 Nurse practitioners; practice without a practice agreement.

Chief patron: Adams, D.M.

Summary as introduced:
Nurse practitioners; practice without a practice agreement. Reduces from five to two the number of years of full-time clinical experience a nurse practitioner must have to be eligible to practice without a written or electronic practice agreement.

HB 1747 Clinical nurse specialist; licensure of nurse practitioners as specialists, etc.

Chief patron: Adams, D.M.

Summary as introduced:
Clinical nurse specialist; licensure; practice. Provides for the licensure of nurse practitioners as clinical nurse specialists by the Boards of Medicine and Nursing and provides that a nurse practitioner licensed as a clinical nurse specialist shall practice pursuant to a practice agreement between the clinical nurse specialist and a licensed physician. The bill requires the Boards of Medicine and Nursing to jointly issue a license to practice as a nurse practitioner in the category of a clinical nurse specialist to an applicant who is an advance practice registered nurse who has completed an advanced graduate-level education program in the specialty category of clinical nurse specialist and who is registered by the Board of Nursing as a clinical nurse specialist on July 1, 2021.

HB 1769 Health care providers, certain; licensure or certification by endorsement.

Chief patron: Freitas

Summary as introduced:
Certain health care providers; licensure or certification by endorsement. Requires the Board of Medicine to issue a license or certificate by endorsement to an applicant who holds a valid, unrestricted license or certificate under the laws of another state, the District of Columbia, or a United States territory or possession with which the Commonwealth has not established a reciprocal relationship upon endorsement by the appropriate board or other appropriate

authority of such other state, the District of Columbia, or United States territory or possession and a determination by the Board of Medicine that the applicant's credentials are satisfactory to the Board of Medicine and the examinations and passing grades required by such other board or authority are fully equal to those required by the Board of Medicine.

HB 1795 Counseling, Board of; licensure of professional counselors without examination.

Chief patron: Cole, M.L.

Summary as introduced:

Board of Counseling; licensure of professional counselors without examination. Requires the Board of Counseling to issue a license as a licensed professional counselor without examination to a person who has applied for such a license and who satisfies all other education, experience, and fitness to practice requirements set forth in regulation and who, in the judgment of the Board, is qualified to practice professional counseling.

HB 1815 Marijuana; legalization of cultivation, manufacture, sale, possession, and testing, penalties.

Chief patron: Heretick

Summary as introduced:

Marijuana; legalization of cultivation, manufacture, sale, possession, and testing; penalties. Establishes a regulatory scheme for the regulation of marijuana cultivation facilities, marijuana manufacturing facilities, marijuana testing facilities, and retail marijuana stores by the Board of Agriculture and Consumer Services. The bill also grants localities the authority to enact ordinances establishing additional licensing requirements for marijuana establishments located within such locality and allows the home cultivation of marijuana for personal use under certain circumstances. The bill imposes a tax on retail marijuana and retail marijuana products sold by a retail marijuana store at a rate of 9.7 percent (for a total sales tax of 15 percent) and provides that 67 percent of the revenues collected from the tax be deposited into the general fund and 33 percent of the revenues be deposited into a "Retail Marijuana Education Support Fund" to be used solely for purposes of public education. Finally, the bill establishes several new criminal penalties related to marijuana, as well as modifies some existing criminal penalties.

HB 1817 Certified nurse midwives; practice.

Chief patron: Adams, D.M.

Summary as introduced:

Practice of certified nurse midwives. Eliminates the requirement that certified nurse midwives practice pursuant to a practice agreement and provides that certified nurse midwives shall practice in accordance with regulations of the Boards of Medicine and Nursing and consistent with the Standards for the Practice of Midwifery set by the American College of Nurse-Midwives and shall consult and collaborate with and refer patients to such other health care providers as may be appropriate for the care of the patient.

HB 1913 Career fatigue and wellness in certain health care providers; programs to address, civil immunity.

Chief patron: Hope

Summary as introduced:

Programs to address career fatigue and wellness in certain health care providers; civil immunity. Expands civil immunity for health care professionals serving as members of or consultants to entities that function primarily to review, evaluate, or make recommendations related to health care services to include health care professionals serving as members of or consultants to entities that function primarily to address issues related to career fatigue and wellness in health care professionals licensed, registered, or certified by the Boards of Medicine, Nursing, or Pharmacy, or in students enrolled in a school of medicine, osteopathic medicine, nursing, or pharmacy located in the Commonwealth. The bill contains an emergency clause.

EMERGENCY

HB 1953 Licensed certified midwives; definition of practice, licensure, report.

Chief patron: Gooditis

Summary as introduced:

Licensed certified midwives; licensure; practice. Defines "practice of licensed certified midwifery" and directs the Boards of Medicine and Nursing to establish criteria for the licensure and renewal of a license as a certified midwife. The bill also directs the Department of Health Professions to convene a workgroup to study the licensure and regulation of certified nurse midwives, certified midwives, and certified professional midwives to determine the appropriate licensing entity for such professionals. The Department shall report its findings and conclusions to the Governor and the General Assembly by November 1, 2021.

HB 1959 Medication abandonment and increasing patient medication adherence; options for reducing rates.

Chief patron: Fowler

Summary as introduced:

Study; Health Professions Subcommittee of the Committee on Health, Welfare and Institutions; options for reducing rates of medication abandonment and increasing patient medication adherence; report. Directs the Health Professions Subcommittee of the Committee on Health, Welfare and Institutions to study options for reducing the rates of medication abandonment and increasing patient medication adherence, including the feasibility of permitting health plans and pharmacy benefits managers to make available in real time to enrollees and their health care providers, upon request of such health care provider made at the time a prescription drug is prescribed to an enrollee, information regarding the actual cost and any benefits of the prescription drug and any health insurance coverage related to the prescription drug.

HB 1987 Telemedicine; coverage of telehealth services by an insurer, etc.

Chief patron: Adams, D.M.

Summary as introduced:

Telemedicine. Clarifies that nothing shall preclude coverage of telehealth services by an insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; a corporation providing individual or group accident and sickness subscription contracts; or a health maintenance organization providing a health care plan for health care services. The bill requires the Board of Medical Assistance Services to amend the state plan for medical assistance to provide for payment of medical assistance for remote patient monitoring services provided via telemedicine for certain high-risk patients, and provides for the establishment of a practitioner-patient relationship via telemedicine for the prescribing of Schedule II through VI controlled substances.

HB 1988 Cannabis oil; processing and dispensing by pharmaceutical processors.

Chief patron: Adams, D.M.

Summary as introduced:

Board of Pharmacy; pharmaceutical processors; processing and dispensing cannabis oil.

Effects numerous changes to the processing and dispensing of cannabis oil by pharmaceutical processors in the Commonwealth. The bill defines the term "designated caregiver facility" and allows any staff member or employee of a designated caregiver facility to assist with the possession, acquisition, delivery, transfer, transportation, and administration of cannabis oil for any patients residing in the designated caregiver facility. The bill allows written certifications for use of cannabis oil to include an electronic practitioner signature. The bill removes the requirement that a cannabis dispensing facility undergo quarterly inspections and instead requires that inspections occur no more than once annually and allows pharmaceutical processors to remediate cannabis oil that fails any quality testing standard. The bill requires pharmaceutical processors to maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. The bill directs the Board of Pharmacy to promulgate regulations implementing the provisions of the bill and regulations creating reasonable restrictions on advertising and promotion by pharmaceutical processors by July 1, 2021.

HB 2005 Disposition of the remains of a decedent; persons to make arrangements for funeral.

Chief patron: Sickles

Summary as introduced:

Disposition of the remains of a decedent; persons to make arrangements for funeral and disposition of remains. Establishes an order of priority for persons who have the right to make arrangements and otherwise be responsible for a decedent's funeral and the disposition of his remains, provided that any such person is 18 years of age or older and of sound mind. The bill sets out, among other things, the circumstances under which such persons forfeit the right to make arrangements and otherwise be responsible for a person's funeral and the disposition of his remains and sets out assertions that a person seeking to exercise the right to make such arrangements must attest to in a signed written statement to be delivered to the funeral service establishment. Any funeral service establishment, funeral service establishment manager of record, funeral service licensee, funeral director, embalmer, registered crematory, registered crematory owner, registered crematory manager of record, or certified crematory operator that relies upon such a written statement shall be immune from civil or criminal liability for any act, decision, or omission in connection with following such person's direction related to the decedent's funeral and the disposition of his remains, unless such act, decision, or omission resulted from willful neglect or bad faith. The bill sets out rights of funeral service establishments when there is a dispute regarding the arrangements of a decedent's funeral or

his remains or the identity of any persons who have the right to make arrangements for the decedent. The bill specifies that the provisions do not apply to cemeteries or cemetery companies.

HB 2039 Physician assistant; eliminates certain requirement for practice.

Chief patron: Rasoul

Summary as introduced:

Practice as a physician assistant. Eliminates the requirement that a physician assistant enter into a practice agreement with a single patient care team physician or patient care team podiatrist and provides that a patient care team physician or patient care team podiatrist shall not be liable for the actions or inactions of a physician assistant for whom the patient care team physician or patient care team podiatrist provides collaboration and consultation. The bill also makes clear that a student physician assistant shall not be required to be licensed to engage in acts that otherwise constitute practice as a physician assistant, provided that the student physician assistant is enrolled in an accredited physician assistant education program.

HB 2044 Naturopathic doctors; Board of Medicine to license and regulate.

Chief patron: Rasoul

Summary as introduced:

Naturopathic doctors; license required. Requires the Board of Medicine to license and regulate naturopathic doctors. The practice of naturopathic medicine is defined in the bill as (i) a system of primary health care for the prevention, diagnosis, and treatment of human health conditions, injury, and disease and (ii) the use of both naturopathic and traditional medical therapies to promote or restore whole patient health. The bill also establishes the Advisory Board on Naturopathic Medicine to assist the Board of Medicine in formulating regulations related to the practice of naturopathic medicine.

HB 2061 VIIS; any health care provider in the Commonwealth that administers immunizations to participate.

Chief patron: Willett

Summary as introduced:

Virginia Immunization Information System; health care entities; required participation. Requires any health care provider in the Commonwealth that administers immunizations to

participate in the Virginia Immunization Information System (VIIS) and report patient immunization history and information to VIIS. Under current law, participation in VIIS is optional for authorized health care entities. The bill has a delayed effective date of January 1, 2022.

HB 2079 Pharmacists; initiation of treatment with and dispensing and administering of drugs and devices.

Chief patron: Rasoul

Summary as introduced:

Pharmacists; initiation of treatment; certain drugs and devices. Expands provisions governing the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists to allow the initiation of treatment with and dispensing and administering of drugs, devices, and controlled paraphernalia to persons 18 years of age or older, in accordance with protocols developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health, and of (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) tuberculin purified protein derivative for tuberculosis testing; (iii) controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and (iv) drugs, devices, controlled paraphernalia, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment. The bill requires any pharmacist who administers a vaccination pursuant to clause (i) to report such administration to the Virginia Immunization Information System. The bill also (a) requires the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, to establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, and controlled paraphernalia by pharmacists in accordance with the provisions of the bill by November 1, 2021; (b) requires the Board of Pharmacy, in collaboration with the Board of Medicine, to adopt regulations within 280 days of the bill's enactment to implement the provisions of the bill; and (c) requires the Board of Pharmacy to continue the work group composed of equal number of representatives of the Boards of Pharmacy and Medicine and other stakeholders to provide recommendations regarding the

developing of protocols for the initiation of treatment with and dispensing and administering of certain drugs and devices by pharmacists to persons 18 years of age or older.

HB 2116 Declared states of emergency, certain; funeral service licensees designated as essential workers.

Chief patron: Mugler

Summary as introduced:

Certain declared states of emergency; essential workers; funeral service licensees; emergency. Provides that in any case in which the Governor has declared a state of emergency related to a communicable disease of public health threat, funeral service licensees shall be considered essential workers and shall be included in any group afforded priority with regard to (i) access to personal protective equipment and (ii) administration of any vaccination against such communicable disease of public health threat during such emergency. The bill contains an emergency clause.

EMERGENCY

HB 2218 Pharmaceutical processors; permits processors to produce & distribute cannabis products.

Chief patron: Hayes

Summary as introduced:

Pharmaceutical processors; cannabis products. Permits pharmaceutical processors to produce and distribute cannabis products other than cannabis oil. The bill defines the terms "botanical cannabis," "cannabis product," and "usable cannabis." The bill requires the Board of Pharmacy to establish testing standards for botanical cannabis and botanical cannabis products, establish a registration process for botanical cannabis products, and promulgate emergency regulations to implement the provisions of the bill. The bill allows the Board of Pharmacy to assess and collect a one-time botanical cannabis regulatory fee from each pharmaceutical processor, not to exceed $50,000, to cover costs associated with the implementation of the provisions of the bill, including costs for new personnel, training, promulgation of regulations and guidance documents, and information technology.

HB 2220 Surgical technologist; certification, use of title.

Chief patron: Hayes

Summary as introduced:

Surgical technologist; certification; use of title. Provides that that no person shall hold himself out to be a surgical technologist or use or assume the title of "surgical technologist" or "certified surgical technologist" unless such person is certified by the Board of Medicine; currently, a person must be registered with the Board of Medicine to use the title "registered surgical technologist." The bill also (i) adds a requirement that an applicant whose certification is based on his holding a current credential as a certified surgical technologist from the National Board of Surgical Technology and Surgical Assisting also demonstrate that he has successfully completed an accredited surgical technologist training program and (ii) provides that the Board of Medicine may certify a person who has practiced as a surgical technologist at any time in the six months prior to July 1, 2021, provided that he registers with the Board of Medicine by December 31, 2021.

HB 2241 Unborn child protection from dismemberment abortion; penalties.

Chief patron: LaRock

Summary as introduced:

Unborn child protection from dismemberment abortion; penalties. Prohibits the practice of dismemberment abortion, which is defined in the bill as meaning to, with the purpose of causing the death of an unborn child, purposely dismember a living unborn child and extract him one piece at a time from the uterus through the use of clamps, grasping forceps, tongs, scissors, or any other instrument that, through the convergence of two rigid levers, slice, crush, or grasp a portion of the unborn child's body to cut or rip such portion of the unborn child's body. The term does not include an abortion that uses suction to dismember the body of an unborn child by sucking fetal parts into a collection container, but it does include an abortion in which a dismemberment abortion is used to cause the death of an unborn child but suction is subsequently used to extract fetal parts after the death of the unborn child. The bill provides that a person who purposely performs a dismemberment abortion is guilty of a Class 4 felony. A cause of action is also created for injunctive relief and civil damages. An exception is made when a dismemberment abortion is necessary to prevent serious health risk to the unborn child's mother.

HB 2259 Governor; issuance of licenses to persons denied by regulatory board.

Chief patron: Scott

Summary as introduced:

Professions and occupations; licensure by Governor. Provides that the Governor may issue a license of the kind granted by a regulatory board under the Department of Professional and Occupational Regulation or the Department of Health Professions to any person whose application for such license to such board has been denied.

HB 2272 Naturopathic doctors; Department of Health Professions to amend its regulations.

Chief patron: Fowler

Summary as introduced:

Department of Health Professions; naturopathic doctors. Directs the Department of Health Professions to amend its regulations to require that a person complete a four-year accredited doctoral program in naturopathy and pass the naturopathy examination administered by the Virginia Naturopathic Doctors Association in order to use the title "Naturopathic Doctor" or "ND." The bill requires the Department to collaborate with the Virginia Naturopathic Doctors Association to draft and implement regulations related to the scope of practice of naturopathic doctors in the Commonwealth.

HJ 531 Interstate Medical Licensure Compact; Joint Com. on Health Care to study advisability of joining.

Chief patron: Helmer

Summary as introduced:

Study; Joint Commission on Health Care; advisability of the Commonwealth's joining the Interstate Medical Licensure Compact; report. Directs the Joint Commission on Health Care to study the advisability of the Commonwealth's joining the Interstate Medical Licensure Compact (the Compact), including the legal effects of joining of the Compact in the Commonwealth and possible positive and negative outcomes resulting from the adoption of the Compact, and develop recommendations as to whether the Commonwealth should join the Compact. The Joint Commission on Health Care shall complete its work by November 30, 2021, and submit an executive report of its findings and conclusions no later than the first day of the 2022 Regular Session of the General Assembly.

SB 1107 Medical malpractice; limitation on recovery.

Chief patron: Stanley

Summary as introduced:

Medical malpractice; limitation on recovery. Eliminates the cap on the recovery in actions against health care providers for medical malpractice where the act or acts of malpractice occurred on or after July 1, 2021.

SB 1115 Industrial hemp; increases maximum THC concentration.

Chief patron: Peake

Summary as introduced:
Industrial hemp; increase maximum THC concentration. Increases the maximum tetrahydrocannabinol (THC) concentration in industrial hemp from the maximum allowed by federal law to the maximum allowed by federal law or one percent, whichever is greater. The bill expands the definition of "hemp product" to include raw materials of any part of the plant Cannabis sativa and omits from such definition the requirement that the product be otherwise lawful.

SB 1167 Nursing, Board of; licensure or certification by endorsement for members of the U.S. military.

Chief patron: Kiggans

Summary as introduced:
Board of Nursing; licensure or certification by endorsement for members of the United States military. Permits the Board of Nursing to issue licenses and certifications by endorsement for registered nurses, licensed practical nurses, and certified nurse aides who hold a similar or equivalent license or certification from the medical corps of a branch of the United States military.

SB 1178 Genetic counseling; repeals conscience clause.

Chief patron: Ebbin

Summary as introduced:
Genetic counseling; conscience clause. Repeals the conscience clause for genetic counselors who forgo participating in counseling that conflicts with their deeply held moral or religious beliefs, provided that they inform the patient and offer to direct the patient to the online directory of licensed genetic counselors maintained by the Board of Medicine. The law being repealed also prohibits the licensing of any genetic counselor from being contingent upon participating in such counseling.

SB 1187 Physical therapy; extends time allowed for a therapist to evaluate and treat patients.

Chief patron: Hashmi

Summary as introduced:

Department of Health Professions; practice of physical therapy. Extends from 30 days to 60 days the time allowed for a physical therapist who has completed a doctor of physical therapy program approved by the Commission on Accreditation of Physical Therapy Education or who has obtained a certificate of authorization to evaluate and treat patients after an initial evaluation without a referral under certain circumstances. The bill also provides that after discharging a patient a physical therapist shall not perform an initial evaluation of a patient without a referral if the physical therapist has performed an initial evaluation of the patient for the same condition within the immediately preceding 60 days.

SB 1189 Occupational therapists; licensure.

Chief patron: Hashmi

Summary as introduced:

Licensure of occupational therapists; Occupational Therapy Interjurisdictional Licensure Compact. Authorizes Virginia to become a signatory to the Occupational Therapy Interjurisdictional Licensure Compact. The Compact permits eligible licensed occupational therapists and occupational therapy assistants to practice in Compact member states provided they are licensed in at least one member state. The bill has a delayed effective date of January 1, 2022, and directs the Board of Medicine to adopt emergency regulations to implement the provisions of the bill. The Compact takes effect when it is enacted by a tenth member state.

SB 1192 Naturopathic doctors; Department of Health Professions to amend its regulations.

Chief patron: Kiggans

Summary as introduced:

Department of Health Professions; naturopathic doctors. Directs the Department of Health Professions to amend its regulations to require that a person complete a four-year accredited doctoral program in naturopathy and pass the naturopathy examination administered by the Virginia Naturopathic Doctors Association in order to use the title "Naturopathic Doctor" or "ND." The bill requires the Department to collaborate with the Virginia Naturopathic Doctors Association to draft and implement regulations related to the scope of practice of naturopathic doctors in the Commonwealth.

SB 1205 Career fatigue and wellness in certain health care providers; programs to address, civil immunity.

Chief patron: Barker

Summary as introduced:

Programs to address career fatigue and wellness in certain health care providers; civil immunity. Expands civil immunity for health care professionals serving as members of or consultants to entities that function primarily to review, evaluate, or make recommendations related to health care services to include health care professionals serving as members of or consultants to entities that function primarily to address issues related to career fatigue and wellness in health care professionals licensed, registered, or certified by the Boards of Medicine, Nursing, or Pharmacy, or in students enrolled in a school of medicine, osteopathic medicine, nursing, or pharmacy located in the Commonwealth. The bill contains an emergency clause.

EMERGENCY

SB 1218 Naturopathic doctors; license required.

Chief patron: Petersen

Summary as introduced:

Naturopathic doctors; license required. Requires the Board of Medicine to license and regulate naturopathic doctors. The practice of naturopathic medicine is defined in the bill as (i) a system of primary health care for the prevention, diagnosis, and treatment of human health conditions, injury, and disease and (ii) the use of both naturopathic and traditional medical therapies to promote or restore whole patient health. The bill also establishes the Advisory Board on Naturopathic Medicine to assist the Board of Medicine in formulating regulations related to the practice of naturopathic medicine.

SB 1268 Disposition of the remains of a decedent; persons to make arrangements for funeral.

Chief patron: Deeds

Summary as introduced:

Disposition of the remains of a decedent; persons to make arrangements for funeral and disposition of remains. Establishes an order of priority for persons who have the right to make

arrangements and otherwise be responsible for a decedent's funeral and the disposition of his remains, provided that any such person is 18 years of age or older and of sound mind. The bill sets out, among other things, the circumstances under which such persons forfeit the right to make arrangements and otherwise be responsible for a person's funeral and the disposition of his remains and sets out assertions that a person seeking to exercise the right to make such arrangements must attest to in a signed written statement to be delivered to the funeral service establishment. Any funeral service establishment, funeral service establishment manager of record, funeral service licensee, funeral director, embalmer, registered crematory, registered crematory owner, registered crematory manager of record, or certified crematory operator that relies upon such a written statement shall be immune from civil or criminal liability for any act, decision, or omission in connection with following such person's direction related to the decedent's funeral and the disposition of his remains, unless such act, decision, or omission resulted from willful neglect or bad faith. The bill sets out rights of funeral service establishments when there is a dispute regarding the arrangements of a decedent's funeral or his remains or the identity of any persons who have the right to make arrangements for the decedent. The bill specifies that the provisions do not apply to cemeteries or cemetery companies.

SB 1320 Licensed certified midwives; definition of practice, licensure, report.

Chief patron: Lucas

Summary as introduced:

Licensed certified midwives; licensure; practice. Defines "practice of licensed certified midwifery" and directs the Boards of Medicine and Nursing to establish criteria for the licensure and renewal of a license as a certified midwife. The bill also directs the Department of Health Professions to convene a workgroup to study the licensure and regulation of certified nurse midwives, certified midwives, and certified professional midwives to determine the appropriate licensing entity for such professionals. The Department shall report its findings and conclusions to the Governor and the General Assembly by November 1, 2021.

SB 1333 Pharmaceutical processors; permits processors to produce & distribute cannabis products.

Chief patron: Lucas

Summary as introduced:

Pharmaceutical processors; cannabis products. Permits pharmaceutical processors to produce

and distribute cannabis products other than cannabis oil. The bill defines the terms "botanical cannabis," "cannabis product," and "usable cannabis." The bill requires the Board of Pharmacy to establish testing standards for botanical cannabis and botanical cannabis products, establish a registration process for botanical cannabis products, and promulgate emergency regulations to implement the provisions of the bill. The bill allows the Board of Pharmacy to assess and collect a one-time botanical cannabis regulatory fee from each pharmaceutical processor, not to exceed $50,000, to cover costs associated with the implementation of the provisions of the bill, including costs for new personnel, training, promulgation of regulations and guidance documents, and information technology.

training, promulgation of regulations and guidance documents, and information technology.

SB 1406 Marijuana; legalization of simple possession; penalties.

Chief patron: Ebbin, Lucas

Summary as introduced:

Marijuana; legalization of simple possession; penalties. Eliminates criminal penalties for possession of marijuana for persons who are 21 years of age or older. The bill also modifies several other criminal penalties related to marijuana and provides for an automatic expungement process for those convicted of certain marijuana-related crimes. The bill establishes a regulatory scheme for the regulation of marijuana cultivation facilities, marijuana manufacturing facilities, marijuana testing facilities, marijuana wholesalers, and retail marijuana stores by the Virginia Alcoholic Beverage Control Authority, renamed as the Virginia Alcoholic Beverage and Cannabis Control Authority. The bill imposes a tax on retail marijuana, retail marijuana products, and marijuana paraphernalia sold by a retail marijuana store, as well as non-retail marijuana and non-retail marijuana products at a rate of 21 percent and provides that localities may by ordinance levy a three percent tax on any such marijuana or marijuana products. The bill provides that net profits attributable to regulatory activities of the Authority's Board of Directors pursuant to this bill shall be appropriated as follows: (i) 40 percent to pre-kindergarten programs for at-risk three and four year olds, (ii) 30 percent to the Cannabis Equity Reinvestment Fund, established in the bill, (iii) 25 percent to substance use disorder prevention and treatment programs, and (iv) five percent to public health programs. The bill creates the Cannabis Control Advisory Board, the Cannabis Equity Reinvestment Board, and the Cannabis Public Health Advisory Council. The bill has a delayed effective date of January 1, 2023, with provisions for the Authority's Board of Directors to promulgate regulations for the implementation of the bill and for implementation of the automatic expungement process to begin in due course. In addition, the bill establishes three work groups to begin their efforts in due course: one focused on public health and safety issues, one focused on providing resources for teachers in elementary and secondary schools, and one focused on college-aged individuals. See S. B. 1406 PDF text: https://lis.virginia.gov/000/CannabisBill.pdf

SB 1408 Joint Commission on Health Care; sunset.

Chief patron: Barker

Summary as introduced:
Joint Commission on Health Care; sunset. Repeals the sunset provision for the Joint Commission on Health Care.

SB 1424 Funeral service establishments; manager of record.

Chief patron: Cosgrove

Summary as introduced:
Funeral service establishments; manager of record. Defines "manager of record" as a person who manages and handles all operations of a licensed funeral service establishment and sets out the conditions under which a funeral service licensee or a funeral director may serve as a manager of record. The bill requires that funeral service establishments employ a full-time manager of record.

SB 1446 Practice of medicine and other healing arts; provision of litigation assistance.

Chief patron: Surovell

Summary as introduced:
Practice of medicine and other healing arts; provision of litigation assistance. Requires practitioners of medicine and other healing arts to provide litigation assistance to treated patients and their attorneys. Such litigation assistance includes providing a legal consult fee schedule upon request, scheduling and participating in meetings with a treated patient's attorney upon request, participating in trial or de bene esse depositions as needed, and providing a written estimate of the cost of the patient's medical services related to the litigation.

From: Jonathan Williams <Jonathan.Williams@easterassociates.com>
Sent: Wednesday, January 20, 2021 10:56 AM
To: kathyscarbalis@hotmail.com <kathyscarbalis@hotmail.com>
Subject: FW: VDH Newborn Screening Program

Hi Kathy,

We received the inquiry below from a VAPA member. Would it be appropriate for the PA Advisory Board to discuss this at the next meeting?

"I am currently a pediatric PA working in Midlothian, VA. Recently, I had attempted to register for the Virginia Newborn Screening Portal in order to gain access to information regarding the newborn screens for my patients when they do not arrive as expected.

I was informed by the laboratory director that according to their partnership with the Virginia Department of Health Professions, access is only provided to doctors, nurse practitioners, and nurse midwives.

Clearly, I feel that this is an oversight by the department and would like to know how to advocate for a change in this policy. As I currently serve as the primary care clinician for a number of patients in our practice, I feel I should have access to their patient information in the same avenue as other health care providers."

Thanks!

Jonathan

Jonathan R. Williams
Executive Director
434-906-1779

1/21/2021

Virginia Administrative Code
Title 12. Health
Agency 5. Department Of Health
Chapter 191. State Plan for the Children with Special Health Care Needs Program

12VAC5-191-260. Scope and content of the Virginia Newborn Screening System.

A. The Virginia Newborn Screening System consists of three components: (i) Virginia Newborn Screening Services, (ii) Virginia Early Hearing Detection and Intervention Program, and (iii) Virginia critical congenital heart disease screening.

B. Virginia Newborn Screening Services.

1. Mission. The Virginia Newborn Screening Services prevents intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by selected inherited disorders.

2. Scope of services. The Virginia Newborn Screening Services provides a coordinated and comprehensive system of services to assure that all infants receive a screening test after birth for selected inherited metabolic, endocrine, and hematological disorders as defined in Regulations Governing Virginia Newborn Screening Services, 12VAC5-71.

These population-based, direct, and enabling services are provided through:

a. Biochemical dried bloodspot screening tests.

b. Follow up of abnormal results.

c. Diagnosis.

d. Education to health professionals and families.

e. Expert consultation on abnormal results, diagnostic testing, and medical and dietary management for health professionals.

Medical and dietary management is provided for the diagnosed cases and includes assistance in accessing specialty medical services and referral to Care Connection for Children.

The screening and management for specified diseases are governed by Regulations Governing Virginia Newborn Screening Services, 12VAC5-71.

3. Criteria to receive Virginia Newborn Screening Services. All infants born in the Commonwealth are eligible for the screening test for selected inherited disorders.

4. Goal. The Title V national performance measures, as required by the federal Government Performance and Results Act (P.L. 103-62), are used to establish the program goals. The following goal shall change as needed to be consistent with the Title V national performance measures:

All infants will receive appropriate newborn bloodspot screening, follow up testing, and referral to services.

C. Virginia Early Hearing Detection and Intervention Program.

1. Mission. The Virginia Early Hearing Detection and Intervention Program promotes early detection of and intervention for infants with congenital hearing loss to maximize linguistic and communicative competence and literacy development.

2. Scope of services. The Virginia Early Hearing Detection and Intervention Program provides services to assure that all infants receive a hearing screening after birth, that infants needing further testing are referred to appropriate facilities, that families have the information that they need to make decisions for their children, and that infants and young children diagnosed with a hearing loss receive appropriate and timely intervention services. These population-based and enabling services are provided through:

a. Technical assistance and education to new parents.

b. Collaboration with physicians and primary care providers.

c. Technical assistance and education to birthing facilities and those persons performing home births.

d. Collaboration with audiologists.

e. Education to health professionals and general public.

Once diagnosed, the infants are referred to early intervention services. The screening and management for hearing loss are governed by the regulation, Regulations for Administration of the Virginia Hearing Impairment Identification and Monitoring System, 12VAC5-80.

3. Criteria to receive services from the Virginia Early Hearing Detection and Intervention Program.

a. All infants born in the Commonwealth are eligible for the hearing screening.

b. All infants who are residents of the Commonwealth and their families are eligible for the Virginia Early Hearing Detection and Intervention Program.

4. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act (P.L. 103-62), are used to establish the program goals. The following goals shall change as needed to be consistent with the Title V national performance measures:

All infants will receive screening for hearing loss no later than one month of age, achieve identification of congenital hearing loss by three months of age, and enroll in appropriate intervention by six months of age.

D. Virginia critical congenital heart disease screening.

1. Mission. Virginia critical congenital heart disease screening promotes early detection of and intervention for newborns with critical congenital heart disease to maximize positive health outcomes and help prevent disability and death early in life.

2. Scope of services. Newborns receive a critical congenital heart disease screening 24 to 48 hours after birth in a hospital with a newborn nursery, as provided in §§ 32.1-65.1 and 32.1-67 of the Code of Virginia and the regulations governing critical congenital heart disease screening (12VAC5-71-210 through 12VAC5-71-260). These population-based, direct, and enabling services are provided through:

a. Critical congenital heart disease screening tests using pulse oximetry or other screening technology as defined in 12VAC5-71-10;

b. Hospital reporting of test results pursuant to § 32.1-69.1 of the Code of Virginia and 12VAC5-71-240; and

c. Follow-up, referral processes, and services, as appropriate, through Care Connection for Children.

3. The screening and management for newborn critical congenital heart disease are governed by 12VAC5-71-210 through 12VAC5-71-260 of the Regulations Governing Virginia Newborn Screening Services.

4. Criteria to receive critical congenital heart disease screening. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive the

screening test for critical congenital heart disease 24 to 48 hours after birth using pulse oximetry or other screening technology.

5. Goal. Except as specified in 12VAC5-71-220 C and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive appropriate critical congenital heart disease screening 24 to 48 hours after birth.

Statutory Authority

§§ 32.1-12 and 32.1-67 of the Code of Virginia.

Historical Notes

Derived from Volume 23, Issue 21, eff. July 25, 2007; amended, Virginia Register Volume 33, Issue 02, eff. October 20, 2016.

1/21/2021

Virginia Administrative Code
Title 12. Health
Agency 5. Department Of Health
Chapter 71. Regulations Governing Virginia Newborn Screening Services

12VAC5-71-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Abnormal screening results" means, in 12VAC5-71-210 through 12VAC5-71-250 only, all results that indicate the newborn has not passed the CCHD screening.

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN pool of funds, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II (18VAC90-30-60 et seq.) of 18VAC90-30 and 18VAC90-30-121, subject to 18VAC90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, as well as a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

"Commissioner" means the State Health Commissioner, his duly designated officer, or agent.

"Confirmatory testing" means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

"Core panel conditions" means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (i) specific and sensitive screening tests, (iii) a sufficiently well understood natural history, and (iii) available and efficacious treatments.

"Critical congenital heart disease" or "CCHD" means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include, but is not limited to, hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"CCHD screening" means the application of screening technology to detect CCHD.

"Department" means the state Department of Health.

"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

"Echocardiogram" means a test that uses an ultrasound to provide an image of the heart.

"Guardian" means a parent-appointed, court-appointed, or clerk-appointed guardian of the person.

"Healthcare provider" means a person who is licensed to provide health care as part of his job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means any facility as defined in § 32.1-123 of the Code of Virginia.

"Infant" means a child less than 12 months of age.

"Licensed practitioner" means a licensed health care provider who is permitted, within the scope of his practice pursuant to Chapter 29 (§ 54.1-2900 et seq.) or Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia, to provide care to a newborn.

"Low protein modified foods" means foods that are (i) specially formulated to have less than one gram of protein per serving, (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, (iii) not natural foods that are naturally low in protein, and (iv) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

"Metabolic formula" means nutritional substances that are (i) prescribed by a health professional with appropriate prescriptive authority; (ii) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (iii) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (iv) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs.

"Metabolic supplements" means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

"Midwife" means a person licensed as a nurse practitioner in the category of certified nurse midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

"Newborn" means an infant who is 28 days old or less who was born in Virginia.

"Newborn nursery" means a general level, intermediate level, or specialty level newborn service as defined in 12VAC5-410-443 B 1, B 2, and B 3.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multistate licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

"Parent" means a biological parent, adoptive parent, or stepparent.

"Pediatric Comprehensive Sickle Cell Clinic Network" means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support services for newborns and children living with sickle cell disease and other genetically related hemoglobinopathies.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state matching funds.

"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.

"Preterm infant" means an infant whose birth occurs by the end of the last day of the 36th week following the onset of the last menstrual period.

"Repeat specimen" means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Satisfactory specimen" means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

"Screened-abnormal" means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

"Screening technology" means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and recommendations issued by the American Academy of Pediatrics, and are approved by the State Board of Health.

"Specialty level nursery" means the same as defined in 12VAC5-410-443 B 3 and as further defined as Level III by the Levels of Neonatal Care, written by the American Academy of Pediatrics Committee on Fetus and Newborn.

"Subspecialty level nursery" means the same as defined in 12VAC5-410-443 B 4.

"Testing laboratory" means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

"Total parenteral nutrition" or "TPN" means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12VAC5-71-30 D.

"Unsatisfactory specimen" means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

"Virginia Genetics Advisory Committee" means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Program and Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

"Virginia Sickle Cell Awareness Program" means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or the sickle cell trait and for such other genetically related hemoglobinopathies.

Statutory Authority

§§ 32.1-12 and 32.1-67 of the Code of Virginia.

Historical Notes

Derived from Volume 23, Issue 13, eff. April 4, 2007; amended, Virginia Register Volume 30, Issue 07, eff. January 24, 2014; Volume 33, Issue 02, eff. October 20, 2016.

1/21/2021

Virginia Administrative Code
Title 12. Health
Agency 5. Department Of Health
Chapter 71. Regulations Governing Virginia Newborn Screening Services

12VAC5-71-50. Responsibilities of the physician or midwife.

For every live birth in the Commonwealth, the physician or midwife in charge of the infant's care after delivery shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12VAC5-71-30 D and in accordance with 12VAC5-71-70 or 12VAC5-71-80.

Statutory Authority

§ 32.1-12 and Article 7 (§ 32.1-65 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from Volume 23, Issue 13, eff. April 4, 2007.

1/21/2021

Virginia Administrative Code
Title 12. Health
Agency 5. Department Of Health
Chapter 71. Regulations Governing Virginia Newborn Screening Services

12VAC5-71-60. Responsibilities of the first attending healthcare provider.

In the event that a physician or midwife does not attend the birth and newborn dried-blood-spot screening tests have not been performed, the first attending healthcare provider shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12VAC5-71-30 D in accordance with 12VAC5-71-110.

Statutory Authority

§ 32.1-12 and Article 7 (§ 32.1-65 et seq.) of Chapter 2 of Title 32.1 of the Code of Virginia.

Historical Notes

Derived from Volume 23, Issue 13, eff. April 4, 2007.

1/21/2021

Virginia Administrative Code
Title 12. Health
Agency 5. Department Of Health
Chapter 71. Regulations Governing Virginia Newborn Screening Services

12VAC5-71-120. Scope and content of Virginia Newborn Screening Program.

A. The mission of Virginia Newborn Screening Program is to prevent intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by those heritable disorders and genetic diseases listed in 12VAC5-71-30 D.

B. The scope of the newborn screening program shall include the following:

1. Ensure that infants born in the Commonwealth receive newborn dried-blood-spot screening, confirmatory testing, and follow-up services for selected heritable disorders or genetic diseases;

2. Locate and track infants with screened-abnormal results or unsatisfactory results, a short-term process of ensuring that the identified healthcare provider is informed of results, in a timely matter, by at least six months of age, to determine if the infant has a selected heritable disorder or genetic disease;

3. Ensure that the department receives all diagnostic test results, both normal and screened-abnormal results, from healthcare providers;

4. Ensure that appropriate diagnostic data are collected, stored, and organized in a secure data management information system that allows for efficient extraction of appropriate data from the testing laboratory to newborn screening services in accordance with federal and state laws and regulations;

5. Assess and evaluate the newborn screening program follow-up activities by collecting and reporting data required annually for Title V national performance measures that address how well the system functions;

6. Educate healthcare providers, parents, and the general public by electronic or written materials and educational sessions, as deemed necessary by the department;

7. Facilitate the entry of infants with screened-abnormal results into medical and dietary management services as needed upon receiving notification from the contracted lab of such results;

8. Ensure that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through the newborn screening program are referred to the Care Connection for Children network for care coordination services; and

9. Provide information to residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through the newborn screening program regarding available assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements that are medically necessary to manage their diagnosed heritable disorder or genetic disease listed in 12VAC5-71-30 D.

C. To ensure full implementation of the newborn screening program, the department may establish contracts with, but not be limited to, the following entities, and the established contracts shall comply with all federal assurances:

1. A designated testing laboratory;

2. Medical facilities to provide metabolic treatment and genetic services; and

3. Other entities as needed.

D. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA; Public Law 103-62), shall be used to establish the newborn screening program goals. The following goals shall change as needed to be consistent with applicable Title V national performance measures:

1. All infants who are born in the Commonwealth and who are residents of Virginia will receive appropriate newborn dried-blood-spot screening, confirmatory testing, and follow-up services.

2. All infants who are born in the Commonwealth and who are not residents of Virginia will receive appropriate newborn dried-blood-spot screening and be referred to their state of residence for confirmatory testing and follow-up services.

Statutory Authority

§§ 32.1-12 and 32.1-67 of the Code of Virginia.

Historical Notes

Derived from Volume 23, Issue 13, eff. April 4, 2007; amended, Virginia Register Volume 30, Issue 07, eff. January 24, 2014.

1/21/2021

Virginia Administrative Code
Title 12. Health
Agency 5. Department Of Health
Chapter 71. Regulations Governing Virginia Newborn Screening Services

12VAC5-71-190. Confidentiality of information.

The department's newborn screening program and its contractors shall maintain, store, and safeguard client records from unauthorized access as required by law.

Statutory Authority

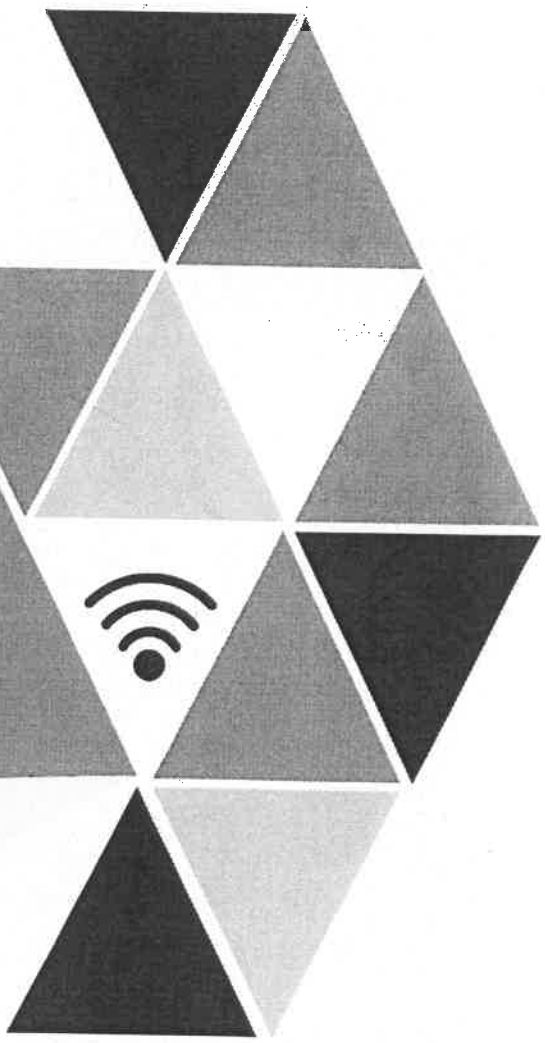
§§ 32.1-12 and 32.1-67 of the Code of Virginia.

Historical Notes

Derived from Volume 23, Issue 13, eff. April 4, 2007; amended, Virginia Register Volume 30, Issue 07, eff. January 24, 2014.

Virginia Early Hearing Detection & Intervention Program

PROTOCOLS FOR PRIMARY CARE PROVIDERS



2018

VDH VIRGINIA DEPARTMENT OF HEALTH

VDHLiveWell

VDH VIRGINIA DEPARTMENT OF HEALTH

Protocol for Primary Care Providers
Virginia Early Hearing Detection and Intervention Program
Virginia Department of Health

This document provides guidance and recommended procedures for Primary Care Providers (PCP) to implement requirements that are specified in the *Code of Virginia*, Section 32.1-64 12VAC5-80[1] and *Regulations for the Administration of the Virginia Hearing Impairment Identification and Monitoring System*[2].

These PCP protocols were first developed in 1999 and revised in 2004 and 2011. The 2018 revision represents the best practice that the Virginia Early Hearing Detection and Intervention Program (VEHDIP) Advisory Committee recommends based on the policy statement *Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs, Joint Committee on Infant Hearing*[3] and other relevant sources such as the Centers for Disease Control and Prevention (CDC), and National Center on Birth Defects and Developmental Disabilities. The VEHDIP Advisory Committee consists of representatives from relevant groups including, but not limited to, primary care physicians, otolaryngologists, audiologists, speech pathologists, nurses, parents and educators of the deaf and hard of hearing. It has been unanimously agreed that Virginia diagnostic PCP protocol standards have followed, and should continue to follow, an exceptional model of evidence-based practice and should reflect an excellence beyond minimal standards of care. This document reflects that philosophy.

It is important to recognize that newborn hearing screening is only one component of a comprehensive approach to the management of childhood hearing loss. It is recommended that the PCP inform the parents or guardian of follow-up diagnostic services, counseling, Part C Early Intervention programs, and parental education and family support organizations. This comprehensive process should be administered by a multidisciplinary team including, but not limited to, audiologists, physicians, educators of the deaf and hard of hearing, speech/language pathologists, nurses, parents and educators of deaf and hard of hearing.

VEHDIP goals are to identify congenital hearing loss by 3 months of age following the CDC *1-3-6 methodology*:

1 – All newborns will be screened for hearing loss **before 1 month** of age.

3 – All newborns who have failed their hearing screen will receive a diagnostic evaluation **before 3 months** of age.

[1] To access the *Code of Virginia* citation, go to: https://law.lis.virginia.gov/admincode/title12/agency5/chapter191/section260/

[2] To access the *Regulations for the Administration of the Virginia Hearing Impairment Identification and Monitoring System,* go to http://leg1.state.va.us/000/reg/TOC12005.HTM#C0080

[3] To access the *Executive Summary for JCIH Year 2007 Position Statement: Principles & Guidelines for Early Hearing Detection and Intervention Programs* go to http://www.asha.org/policy/PS2007-00281.htm

6 – All infants diagnosed with hearing loss will be enrolled in early intervention services **before 6 months** of age

I. Virginia Early Hearing Detection and Intervention Program Overview

The Virginia Early Hearing Detection and Intervention Program is required to collect, maintain, and evaluate hearing screening data. Program staff must provide follow-up, including communicating with the parent or guardian to assure that they have the information needed to seek timely and appropriate follow-up services. They should provide training and technical assistance to hospitals, audiologists and PCPs. Lastly, the program is required to review and evaluate the surveillance system including follow-up rates, false-positive rates, false-negative rates, referral mechanisms and effectiveness of tracking.

Best practice guidelines for the VEHDIP include:

- Monitor hospital data and rate of reporting.
- Provide epidemiological analysis of the data for planning and program management purposes.
- Provide training and technical assistance to birthing centers.

Providers performing initial hearing screening are required to perform this screen prior to hospital discharge, and should report results within seven days but no later than fourteen days after discharge to the Virginia Department of Health (VDH) and to the PCP from whom the infant will receive care after discharge. They must provide written information to the parent that includes the benefits of newborn hearing screening, the procedures used for screening, and recommendations for further follow up. A list of audiologic providers can be accessed on EHDIPALS.org or a list of pediatric audiologists can be found on the back of all the VEHDIP letters to parents and PCPs.

A. Reporting

The required methodology for reporting initial newborn hearing screenings to the VDH is via the Virginia Infant Screening and Infant Tracking System (VISITS) database. If a provider is unable to enter results into VISITS, they may use the Audiological Reporting Form—including test results, diagnosis, and recommendations—and submit to the VDH within seven days but no later than fourteen days of the testing. The Audiological Reporting Form, including risk indicators and instructions, can be downloaded from the VDH website www.vahealth.org/hearing.

Best practice guidelines for PCPs:

- Review the hearing screening results and risk indicator findings from hospitals.
- Referral of infants who fail the initial screen immediately to a pediatric audiologist for a repeat hearing screening or diagnostic assessment.
- Obtain and review the diagnostic evaluation results from audiological providers.
- Ensure infants with a hearing loss diagnosis receive a referral for evaluation by an otolaryngologist, at least one examination to assess visual acuity by a pediatric ophthalmologist, and for genetic testing and counseling.

- Ensure that parents are informed and/or advised about enrollment into Part C Early Intervention, preferably by six months of age. Visit the Infant & Toddler Connection of Virginia website www.infantva.org for information on referral processes and contacts.
- Screen and refer infants diagnosed with persistent conductive hearing loss secondary to otitis media with effusion for otolaryngology and audiological assessment for confirmation of diagnosis to avoid delayed diagnosis of sensorineural hearing loss.
- Refer directly to an audiologist for rescreening NICU infants who do not pass an automated ABR. For rescreening, a complete screening of both ears is recommended even if only one ear failed the initial screening.
- All infants readmitted in the first month of life, when there are conditions associated with potential of hearing loss (such as exchange transfusions for hyperbilirubinemia or confirmed sepsis) need to have audiological testing.
- All infants and toddlers should have an objective developmental screen with a standardized tool at 9-, 18-, and 24-to-30 months of age or at any time the healthcare professional or family has concerns about speech or language skills.
- Refer infants and toddlers who do not pass the speech-language portion of a standardized developmental screen, or whose behavior/responses cause concern regarding hearing or language, for speech-language evaluation and audiology assessment.

Persons providing hearing or audiological services to infants **after** hospital discharge are required to provide the screening or evaluation results to the parent or guardian and to the child's primary care provider. If a PCP provides office-based hearing screenings, the PCP is responsible to ensure that the screening is done on the same equipment as was used for the initial hearing screening. The PCP should **only conduct one** rescreening in the office.

A variety of technologies are available to identify hearing loss in the first days of life. These techniques are physiological measures of the status of the peripheral auditory system that are highly correlated with hearing status. The two methodologies generally accepted as effective for universal newborn screening are:

1) **Auditory brainstem response (ABR)** – reflects the activity of the cochlea, auditory nerve, and auditory brainstem pathways. **For use in NICU and/or well baby nursery.**

2) **Otoacoustic emissions (OAE)** – reflects sensitivity to outer hair cell dysfunction. **For use in well baby nursery.**

Infants who fail hearing screening in one or both ears using ABR testing should not be re-screened using OAE testing. OAE is not sufficient to rule out Auditory Neuropathy. Due to the increased incidence of auditory neuropathy in the neonatal intensive care unit (NICU) patient population, newborns who receive this level of care should have both ears screened using ABR testing prior to discharge or transfer to a lower level of newborn services. Immitance testing may help distinguish conductive or mixed hearing loss from sensorineural hearing loss (SNHL).

II. Interpretation of Hearing Screen Results

Table I summarizes information on hearing screen results and associated primary healthcare provider (PHP) actions.

Table I: Interpretation of Hearing Screen Results

Screening Result	Interpretation by PCP	PCP Follow-up Recommendations
Passed Screen	Infant passed in both ears	Monitor communication and language development.
Passed with Risk	Infant passed in both ears but is at risk for progressive or late onset hearing loss	Inform the parent of the need for a diagnostic audiological assessment between 12 to 24 months of age. Perform developmental surveillance and screening consistent with American Academy of Pediatrics recommendations and refer as needed. Early and more frequent assessments may be indicated for children with CMV syndromes and syndromes at risk for late onset of hearing loss.
Missed Screen	Infant was not screened before discharge from the hospital.	Advise the parents that screening needs to be completed immediately.
Failed Screen	Infant did not pass in one or both ears	Infants who fail Automated Auditory Brainstem Response (AABR) testing should not be rescreened by OAE testing, because they are presumed at risk for a subsequent diagnosis of auditory neuropathy/dyssynchrony. Infants should be tested again using AABR no later than one month after hospital discharge. Ensure that any infant failing their hearing screen or rescreen is referred to a pediatric audiologist as soon as possible. Refer to EHDI-PALS at http:ehdipals.org for resources.
Infant not born in a hospital	Any infant born outside of hospital facility, e.g., home birth	Refer for initial hearing screening as soon as possible after birth.
NICU Infants	Infants admitted to the NICU	All Infants admitted to NICU should be screened with AABR. If infants are admitted to the NICU > 5 days and pass the AABR then further follow up is

		needed for potential delayed onset of hearing loss. See Pass with Risk above for recommendations on follow up.

A flow chart depicting the newborn hearing screening and follow-up process is in **Attachment 1**.

III. PCP Recommended Actions for Infants with Confirmed Hearing Loss

Every infant with confirmed hearing loss needs medical evaluation to determine the etiology of hearing loss, identify related physical conditions, and make recommendations for treatment and referrals to other resources. Relevant professionals should give resource information to the parent (or guardian) of any child found to have a hearing loss, including but not limited to, the degrees and effects of hearing loss, communication options, amplification options, the importance of medical follow-up, and agencies and organizations that provide services to children with hearing loss and their families. The primary healthcare provider should thoroughly document family history and the mother's prenatal risk factors. This will support ongoing care for the child as well as monitoring other children in the family. Document:

- Prenatal conditions: ototoxic medication exposure, pregnancy complications, immunization status of mother for rubella, maternal status for syphilis, maternal drug and/or alcohol use, and history of frequent spontaneous abortions.
- Family history: hereditary childhood sensorineural hearing loss and family members with permanent hearing loss with onset before age 30 not related to trauma or medical condition.

Complete a physical examination with special attention to:

- Minor anomalies: unusual morphologic features occurring in less than 5% of the population with no cosmetic or functional significance.
- Major anomalies: dysmorphic features that cause significant cosmetic or functional abnormality, such as cleft palate, cardiac, limb, or other skeletal deformities.
- Poor growth, microcephaly, or abnormal neurological exam.

Obtain laboratory and imaging studies:

- Urine culture or oral polymerase chain reaction (PCR) swab for cytomegalovirus (CMV) before aged 2 weeks if prenatal CMV infection is suspected.
- Testing for rubella, syphilis, or toxoplasmosis consistent with history of findings and immunization status of mothers.
- EKG if cardiac condition suspected.
- Skeletal survey if growth delayed or disproportionate.
- Head CT or MRI if neurological exam abnormal. Temporal bone CT or MRI may be indicated after obtaining other laboratory or audiological testing to evaluate for inner ear abnormalities that would complicate further care recommendations (i.e. cochlear implantation).

Refer as follows:

- To otolaryngology (ENT).
- To ophthalmology/cardiology/nephrology evaluation if indicated.

- For genetic evaluation:
  - If there are significant dysmorphic features.
  - A connexin gene assay where there is a family history of deafness
  - Siblings with increased risk of having hearing loss for an audiological evaluation. Most important if moderate-to-severe-to-profound bilateral SNHL.
- To a parent to parent support organization.

IV. Risk Indicators

Birth hospitals in Virginia are responsible for determining the risk status for hearing loss on every newborn regardless of the results of the hearing screen. Risk-status data assist with monitoring for progressive, delayed-onset, and/or conductive hearing loss. VDH recognizes the risk indicators identified by the policy statement *Year 2007 Position Statement: Principles and Guidelines for Early Detection and Intervention Programs, Joint Committee on Infant Hearing* (See **Attachment 2**).
Some indicators may not be determined during the course of the hospital stay. Therefore, infants and young children who have late-onset or late-identified risk indicators should be monitored for speech, language, and hearing developmental milestones by the primary healthcare provider during well-child visits.

The following diagram summarizes processes that should be followed to ensure infants and children who are at risk for hearing loss receive appropriate audiological follow-up.

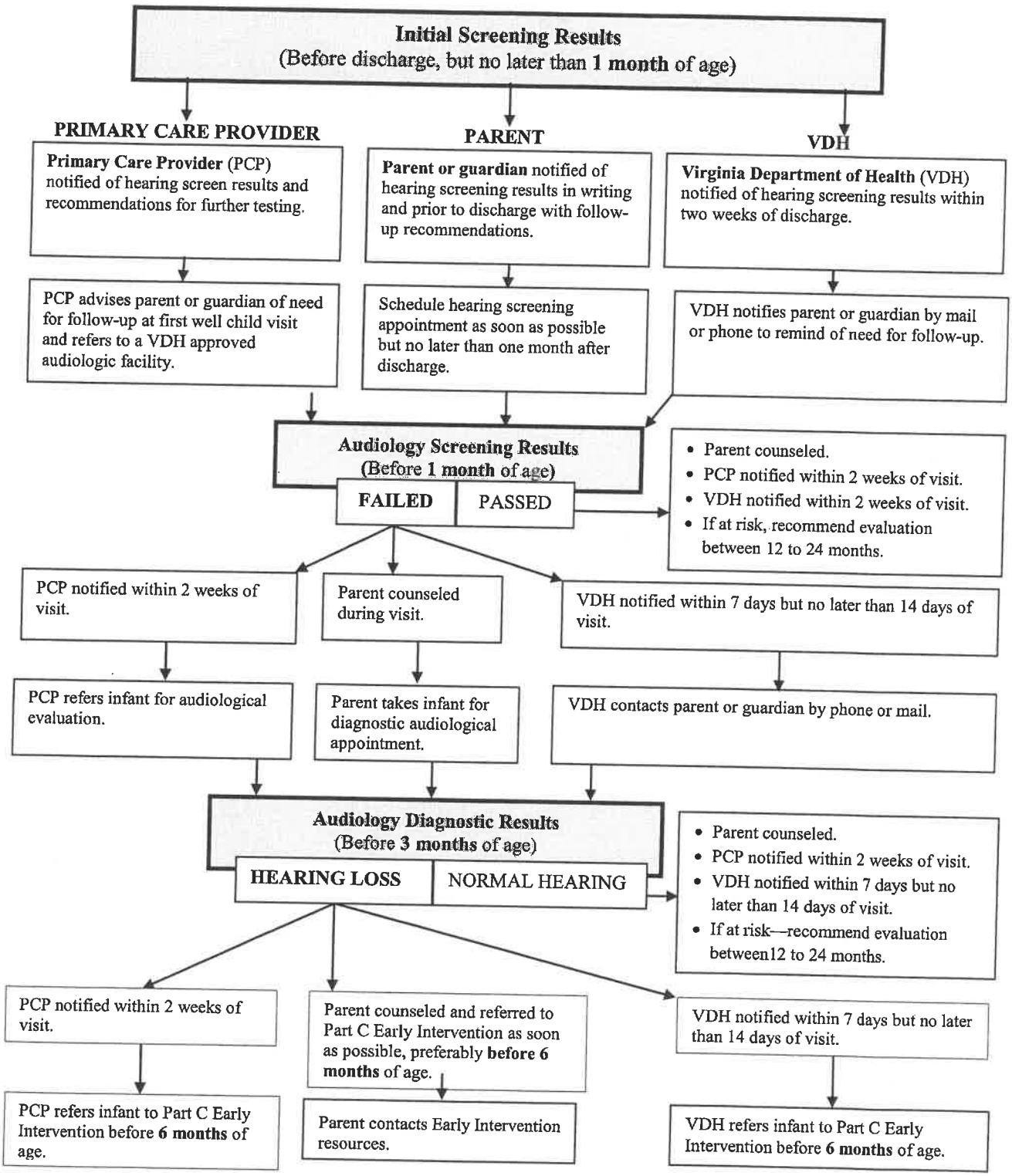
Some of these indicators are not present and/or would not be identified in the newborn period. These include parental concern and some neurodegenerative disorders or sensory motor neuropathies. These are included in the risk indicator list because parents and physicians should be informed about all indicators that can contribute to development of hearing loss beyond the newborn period. The child's physician is to report risk indicators which are identified after the newborn period to the VEHDIP in order to allow for follow-up.

V. Contacts

For more information or further assistance, families are encouraged to contact:
Virginia Department of Health
Office of Family Health Services
Virginia Early Hearing Detection and Intervention Program
109 Governor Street, 9th Floor
Richmond, VA 23219
Phone: Toll Free 1-866-493-1090 TTY 7-1-1
Fax: 804-864-7771
Website: newbornhearingtestva.com

VI. Attachments

Attachment I: Virginia Early Hearing Detection and Intervention Program Process Flow Chart



Attachment 2: Risk Indicators for Progressive or Delayed-Onset Hearing Loss

(For Use with Neonates and Infants Through 2 Years of Age)

Family history of permanent childhood hearing loss

- Mother of child
- Father of child
- Sister of child
- Brother of child
- Grandmother of child
- Grandfather of child
- Aunt of child
- Uncle of child
- 1st cousin of child
- More than one relative of the same parent

Stigmata or other findings associated with a syndrome known to include a sensorineural or conductive hearing loss or Eustachian tube dysfunction

- Branchio-oto-renal (BOR)
- Noonan
- CHARGE association
- Pierre Robin
- Rubenstein-Taybi
- Stickler
- Williams
- Zellweger
- Goldenhar (oculo-auriculo-vertebral or OAV)
- Trisomy 8 – Warkany syndrome
- Trisomy 21 – Down syndrome
- Trisomy 18 – Edwards syndrome
- Trisomy 13 – Patau syndrome
- Trisomy 9 – Mosaic syndrome

Postnatal infections associated with sensorineural hearing loss

- Confirmed bacterial meningitis
- Confirmed viral meningitis

In utero infections

- Cytomegalovirus
- Herpes
- Rubella
- Syphilis
- Toxoplasmosis
- Zika

Neonatal indicators

- Intensive care greater than (>) 5 days
- Extracorporeal membrane oxygenation (ECMO)
- Exposure to ototoxic medications: at risk aminoglycoside exposure
- Mechanical ventilation
- Hyperbilirubinemia requiring exchange transfusion

Syndromes associated with progressive hearing loss

- Neurofibromatosis
- Osteopetrosis
- Alport
- Jervell & Lange-Nielson
- Waardenburg
- Pendred
- Usher

Neurodegenerative disorders, such as

- Hunter syndrome
- Charcot-Marie-Tooth syndrome
- Friedreich's ataxia

Head trauma requiring hospitalization

- Basal skull/temporal bone fracture

Other – specify if chosen

Parental or caregiver concern regarding hearing, speech, language, and/or developmental delay

Craniofacial Anomalies

- Pinna
- Cleft palate
- Atresia
- Microtia
- Choanal atresia
- Temporal bone anomalies

Chemotherapy

Based on *Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs, Joint Committee on Infant Hearing.*

Protocol for Primary Healthcare Providers
Virginia Early Hearing Detection and Intervention Program
Virginia Department of Health

Approved by:

Marissa Levine, MD, MPH
State Health Commissioner

3/16/18
Date

An Agency of the Commonwealth of Virginia

Virginia.gov (https://www.virginia.gov) Find an Agency (https://www.virginia.gov/agencies)

Virginia
Department of General Services

Serving Government. Serving Virginians.

(/link/5ae4595c616f4c29bcb8d748e87068d4.aspx)

jobs (https://virginiajobs.peopleadmin.com/postings/search?
=√&query=&query_v0_posted_at_date=&435=&624=&628=&693=54&625=&626=&627=&696=&commit=Search)
(https://eva.virginia.gov/) (https://twitter.com/dgsvirginia)
https://www.youtube.com/user/DGSVirginia)
https://www.linkedin.com/company/virginia-department-of-general-services)

Search DGS

I Want To...

I'm Looking For...

I Need to Contact...

Search DCLS

Division of **Consolidated Laboratory Services**

About DCLS

Lab Certification/Accreditation

Lab Testing

Lab Services

Resources

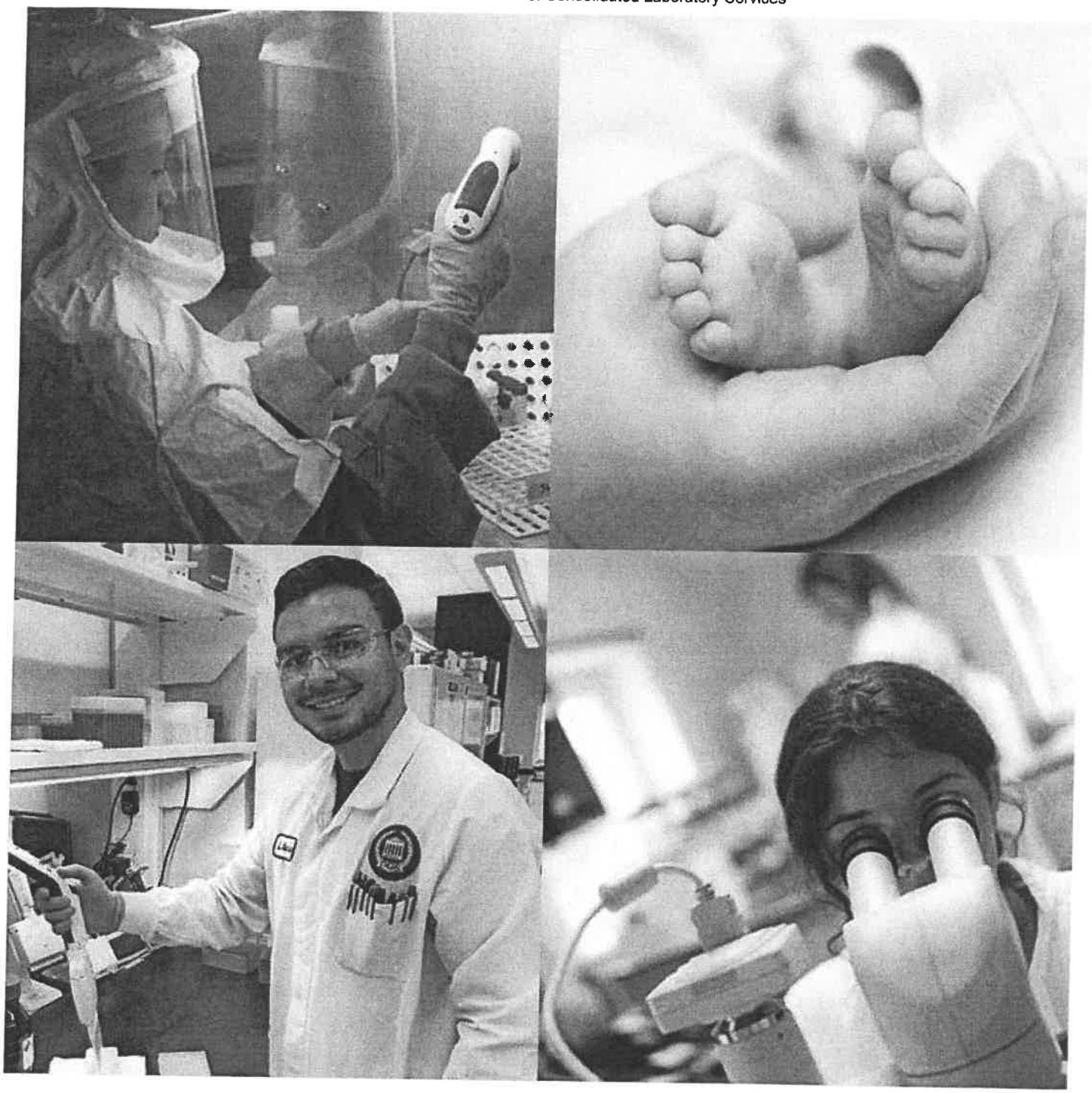
Updates

DCLS Jobs

Forms & Documents

Contacts

LABORATORY SERVICES



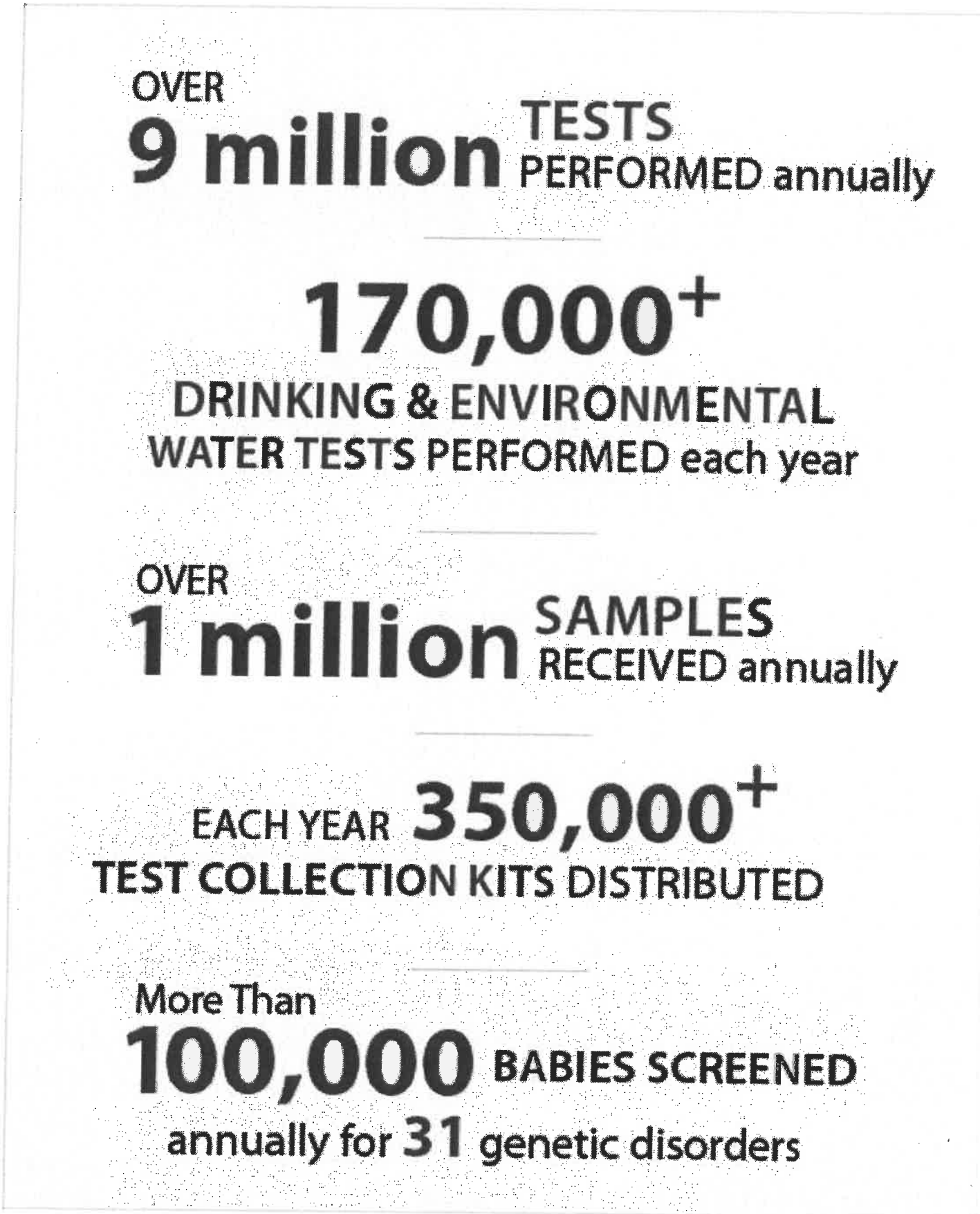
The Division of Consolidated Laboratory Services (DCLS) provides around-the-clock, high quality analytical testing services and support to local, state and federal agencies that serve to protect the health, safety and security of the public. The State Laboratory also is a national training "Center of Excellence" for the U.S. Centers for Disease Control and Prevention and the U.S. Department of Agriculture and provides certification and accreditation for other laboratories.

Testing available at DCLS includes:

- Newborn screening
- Infectious disease outbreaks
- Foodborne outbreaks

- Drugs of Abuse
- Chemical and biological warfare agents
- Drinking and environmental waters
- Soil and sediment
- Radioactive materials
- Food chemistry
- Animal feed, fertilizers, etc.

BY THE NUMBERS



See what our employees are saying about working at DGS (/division-of-consolidated-laboratory-services/dcls-jobs/what-our-employees-are-saying/)

Department of General Services (/)

Director: Joe Damico

Deputy Director: Sandra Gill

Deputy Director: Matthew James

1100 Bank Street, Suite 420

Richmond, Virginia 23219

Phone: (804) 786-3311

Fax: (804) 371-8305

Contact Us (/dgs/contacts/dgs-contacts/)

(https://www.dvsv3.com/)

(http://www.govtech.com/cdg/digital-government-achievement/Government-Experience-Awards-2017-Inaugural-Winners-Announced.html)

(http://contests.gdusa.com/2017-american-web-design-awards/awda17winner)

(http://www.webaward.org/category/Government/best-government-websites.html#.WcrF-1tSxhF)

eVA Transparency in Procurement (https://logi.epro.cgipdc.com/Public/rdPage.aspx)

Expenditures (http://datapoint.apa.virginia.gov/dashboard.php) Organizational Chart (/dgs/contacts/org-chart/)

Privacy & Security (/dgs/resources/web-policies/privacy--security/) WAI Compliance (/dgs/resources/web-policies/WIA-compliance/)