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HOUSE BILL NO. 829

Offered January 11, 2012

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A BILL to amend and reenact §§ 32.1-46.01, 32.1-46.1, 32.1-64.1, 32.1-64.2, 32.1-65, 32.1-67, and 32.1-67.1 of the Code of Virginia, relating to the Virginia Immunization Information System.

Patron—Farrell

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-46.01, 32.1-46.1, 32.1-64.1, 32.1-64.2, 32.1-65, 32.1-67, and 32.1-67.1 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-46.01. Virginia Immunization Information System.

A. The Board of Health shall establish the Virginia Immunization Information System (VIIS), a statewide immunization registry that consolidates patient immunization histories from birth to death into a complete, accurate, and definitive record that may be made available to participating health care providers throughout Virginia, to the extent funds are appropriated by the General Assembly or otherwise made available. The purposes of VIIS shall be to (i) protect the public health of all citizens of the Commonwealth, (ii) prevent under- and over-immunization of children, (iii) ensure up-to-date recommendations for immunization scheduling to health care providers and the Board, (iv) generate parental reminder and recall notices and manufacturer recalls, (v) develop immunization coverage reports, (vi) identify areas of under-immunized population, and (vii) provide, in the event of a public health emergency, a mechanism for tracking the distribution and administration of immunizations, immune globulins, or other preventive medications or emergency treatments.

B. The Board of Health shall promulgate regulations to implement the VIIS that shall address:

1. Registration of voluntary participants, including, but not limited to, a list of those health care entities that are authorized to participate and any forms and agreements necessary for compliance with the regulations concerning patient privacy promulgated by the federal Department of Health and Human Services;

2. Procedures for confirming, continuing, and terminating participation and disciplining any participant for unauthorized use or disclosure of any VIIS data;

3. Procedures, timelines, and formats for reporting of immunizations by participants;

4. Procedures to provide for a secure system of data entry that may include encrypted online data entry or secure delivery of data files;

5. Procedures for incorporating the data reported on children's immunizations pursuant to subsection E of § 32.1-46;

6. The patient identifying data to be reported, including, but not limited to, the patient's name, date of birth, gender, telephone number, home address, birth place, and mother's maiden name;

7. The patient immunization information to be reported, including, but not necessarily limited to, the type of immunization administered (specified by current procedural terminology (CPT) code or Health Level 7 (HL7) code); date of administration; identity of administering person; lot number; and if present, any contraindications, or religious or medical exemptions;

8. Mechanisms for entering into data-sharing agreements with other state and regional immunization registries for the exchange, on a periodic nonemergency basis and in the event of a public health emergency, of patient immunization information, after receiving, in writing, satisfactory assurances for the preservation of confidentiality, a clear description of the data requested, specific details on the intended use of the data, and the identities of the persons with whom the data will be shared;

9. Procedures for the use of vital statistics data, including, but not necessarily limited to, the linking of birth certificates and death certificates;

10. Procedures for requesting immunization records that are in compliance with the requirements for disclosing health records set forth in § 32.1-127.1:03; such procedures shall address the approved uses for the requested data, to whom the data may be disclosed, and information on the provisions for disclosure of health records pursuant to § 32.1-127.1:03;

11. Procedures for releasing aggregate data, from which personal identifying data has been removed or redacted, to qualified persons for purposes of research, statistical analysis, and reporting; and

12. Procedures for the Commissioner of Health to access and release, as necessary, the data contained in VIIS in the event of an epidemic or an outbreak of any vaccine-preventable disease or the potential epidemic or epidemic of any disease of public health importance, public health significance, or

public health threat for which a treatment or vaccine exists.

The Board's regulations shall also include any necessary definitions for the operation of VIIS; however, "health care entity," "health care plan," and "health care provider" shall be as defined in subsection B of § 32.1-127.1:03.

C. The establishment and implementation of VIIS is hereby declared to be a necessary public health activity to ensure the integrity of the health care system in Virginia and to prevent serious harm and serious threats to the health and safety of individuals and the public. Pursuant to the regulations concerning patient privacy promulgated by the federal Department of Health and Human Services, covered entities may disclose protected health information to the secure system established for VIIS without obtaining consent or authorization for such disclosure. Such protected health information shall be used exclusively for the purposes established in this section.

D. The Board and Commissioner of Health, any employees of the health department, any voluntary participant, and any person authorized to report or disclose immunization data hereunder shall be immune from civil liability in connection therewith unless such person acted with gross negligence or malicious intent.

E. This section shall not diminish the responsibility of any physician or other person to maintain accurate patient immunization data or the responsibility of any parent, guardian, or person standing in loco parentis to cause a child to be immunized in accordance with the provisions of § 32.1-46. Further, this section shall not be construed to require the immunization of any person who objects thereto on the grounds that the administration of immunizing agents conflicts with his religious tenets or practices, or any person for whom administration of immunizing agents would be detrimental to his health.

F. The Commissioner may authorize linkages between VIIS and other secure electronic databases that contain health records reported to the Department of Health, subject to all state and federal privacy laws and regulations. These health records may include newborn screening results reported pursuant to § 32.1-65, newborn hearing screening results reported pursuant to § 32.1-64.1, and blood-lead level screening results reported pursuant to § 32.1-46.1. Health care providers authorized to use VIIS may view the health records of individuals to whom the providers are providing health care services.

§ 32.1-46.1. Board to establish protocol for identification of children with elevated blood-lead levels.

The Board shall promulgate regulations establishing a protocol for the identification of children at risk for elevated blood-lead levels which shall (i) require blood-lead level testing at appropriate ages and frequencies, when indicated, (ii) provide for criteria for determining low risk for elevated blood-lead levels and when such blood-lead level testing is not indicated, and (iii) require physicians to make available to parents information on the dangers of lead poisoning, along with a list of available resources, as part of regular well check visits for all children.

As deemed necessary by the Board, the protocol may also address follow-up testing for children with elevated blood-lead levels, dissemination of the protocol or other information to relevant health care professionals, appropriate information for parents, and other means of preventing lead poisoning among children. In promulgating such regulations, the Board shall consider the guidelines of the Centers for Disease Control and Prevention and may consider such other materials relating to lead poisoning prevention, testing, and treatment as it deems appropriate. *The Board may also establish procedures governing how health care providers and laboratories report results to the Department of Health.*

The Commissioner may authorize linkages between secure electronic data systems maintained by the Department of Health containing blood-lead level records and the Virginia Immunization Information System (VIIS) operated pursuant to § 32.1-46.01. The Commissioner may authorize health care providers authorized to view VIIS to view blood-lead level records of individuals to whom the providers are providing health care services. The records may be made available until the child reaches seven years of age, after which the records shall not be made available through a linkage to VIIS. Such linkages shall be subject to all applicable state and federal privacy laws and regulations.

§ 32.1-64.1. Virginia Hearing Impairment Identification and Monitoring System.

A. In order to identify hearing loss at the earliest possible age among newborns and to provide early intervention for all infants so identified as having hearing impairment, the Commissioner shall establish and maintain the Virginia Hearing Impairment Identification and Monitoring System. This system shall be for the purpose of identifying and monitoring infants with hearing impairment to ensure that such infants receive appropriate early intervention through treatment, therapy, training and education.

B. The Virginia Hearing Impairment Identification and Monitoring System shall be initiated in all hospitals with neonatal intensive care services, in all hospitals in the Commonwealth having newborn nurseries, and in other birthing places or centers in the Commonwealth ~~having newborn nurseries~~.

C. In all hospitals with neonatal intensive care services, the chief medical officer of such hospitals or his designee shall identify infants at risk of hearing impairment using criteria established by the Board. Beginning on July 1, 1999, all infants shall be given a hearing screening test, regardless of whether or not the infant is at risk of hearing impairment, by the chief medical officer or his designee using

methodology approved by the Board. The test shall take place before the infant is discharged from the hospital to the care of the parent or guardian, or as the Board may by regulation provide.

In all other hospitals and other birthing places or centers, the chief medical officer or his designee or the attending practitioner shall identify infants at risk of hearing impairment using criteria established by the Board.

D. Beginning on July 1, 2000, the Board shall provide by regulation for the giving of hearing screening tests for all infants born in all hospitals. The Board's regulations shall establish when the testing shall be offered and performed and procedures for reporting.

An infant whose hearing screening indicates the need for a diagnostic audiological examination shall be offered such examination at a center approved by the Board of Health. As a condition of such approval, such centers shall maintain suitable audiological support and medical and educational referral practices.

E. The Commissioner shall appoint an advisory committee to assist in the design, implementation, and revision of this identification and monitoring system. The advisory committee shall meet at least four times per year. A chairman shall be elected annually by the advisory committee. The Department of Health shall provide support services to the advisory committee. The advisory committee shall consist of representatives from relevant groups including, but not limited to, the health insurance industry; physicians, including at least one pediatrician or family practitioner, one otolaryngologist, and one neonatologist; nurses representing newborn nurseries; audiologists; hearing aid dealers and fitters; teachers of the deaf and hard-of-hearing; parents of children who are deaf or hard-of-hearing; adults who are deaf or hard-of-hearing; hospital administrators; and personnel of appropriate state agencies, including the Department of Medical Assistance Services, the Department of Education, and the Department for the Deaf and Hard-of-Hearing. The Department of Education, the Department for the Deaf and Hard-of-Hearing, and the Department of Behavioral Health and Developmental Services shall cooperate with the Commissioner and the Board in implementing this system.

F. With the assistance of the advisory committee, the Board shall promulgate such rules and regulations as may be necessary to implement this identification and monitoring system. These rules and regulations shall include criteria, including current screening methodology, for the identification of infants (i) with hearing impairment and (ii) at risk of hearing impairment and shall include the scope of the information to be reported, reporting forms, screening protocols, appropriate mechanisms for follow-up, relationships between the identification and monitoring system and other state agency programs or activities and mechanisms for review and evaluation of the activities of the system. The identification and monitoring system shall collect the name, address, sex, race, and any other information determined to be pertinent by the Board, ~~regarding infants determined to be at risk of hearing impairment or to have hearing loss~~ *for infants who are screened pursuant to this section*.

G. In addition, the Board's regulations shall provide that any person making a determination that an infant (i) is at risk for hearing impairment, (ii) has failed to pass a hearing screening, or (iii) was not successfully tested shall notify the parent or guardian of the infant, the infant's primary care practitioner, and the Commissioner. *The Board may provide guidelines for the notification process.*

H. No testing required to be performed or offered by this section shall be performed if the parents of the infant object to the test based on their bona fide religious convictions.

§ 32.1-64.2. Confidentiality of records; publication; Commissioner required to contact parents, physicians, and relevant local early intervention program.

The Commissioner and all other persons to whom data is submitted pursuant to § 32.1-64.1 shall keep such information confidential. No publication ~~of information shall be made except in the form of statistical or other studies which do not identify individuals~~ *of research or statistical data shall be made that identifies any infant with hearing impairment or risk of hearing impairment*. ~~However, the~~ *The* Commissioner shall contact the parents of children identified with hearing impairment or at risk of hearing impairment, their physicians and the relevant local early intervention program to provide them with information about available public and private health care and educational resources including any hearing impairment clinics.

The Commissioner may authorize linkages between secure electronic data systems maintained by the Department of Health containing newborn hearing screening records and the Virginia Immunization Information System (VIIS) operated pursuant to § 32.1-46.01. The Commissioner may authorize health care providers authorized to view VIIS to view newborn hearing screening records of individuals to whom the providers are providing health care services. The records may be made available until the child reaches seven years of age, after which the records shall not be made available through a linkage to VIIS. Such linkages shall be subject to all applicable state and federal privacy laws and regulations.

§ 32.1-65. Certain newborn screening required.

In order to prevent mental retardation and permanent disability or death, every infant who is born in the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not

necessarily identical to, the uniform condition panel recommended by the ~~American College of Medical Genetics in its report, Newborn Screening: Toward a Uniform Screening Panel and System, that was produced for the U.S. Department of Health and Human Services. Further, upon the issuance of guidance for states' newborn screening programs by the federal Department of Health and Human Services, every infant who is born in the Commonwealth shall be screened for a panel of disorders consistent with, but not necessarily identical to, the federal guidance document~~ *U.S. Secretary of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children*.

Any infant whose parent or guardian objects thereto on the grounds that such tests conflict with his religious practices or tenets shall not be required to receive such screening tests.

The physician or certified nurse midwife in charge of the infant's care after delivery shall cause such tests to be performed. The screening tests shall be performed by the Division of Consolidated Laboratory Services or any other laboratory the Department of Health has contracted with to provide this service.

The program for screening infants for sickle cell diseases shall be conducted in addition to the programs provided for in Article 8 (§ 32.1-68 et seq.) ~~of this chapter~~.

§ 32.1-67. Duty of Board for follow-up and referral protocols; regulations.

Infants identified with any condition for which newborn screening is conducted pursuant to § 32.1-65 shall be eligible for the services of the Children with Special Health Care Needs Program administered by the Department of Health. The Board of Health shall promulgate such regulations as may be necessary to implement Newborn Screening Services and the Children with Special Health Care Needs Program. The Board's regulations shall include, but not be limited to, a list of newborn screening tests conducted pursuant to § 32.1-65, *notification processes conducted pursuant to § 32.1-66*, follow-up procedures, appropriate referral processes, and services available for infants and children who have a heritable disorder or genetic disease identified through Newborn Screening Services.

§ 32.1-67.1. Confidentiality of records; prohibition of discrimination.

The results of the newborn screening services conducted pursuant to this article may be used for research and collective statistical purposes. No publication of ~~information, biomedical~~ research~~,~~ or ~~medical~~ *statistical* data shall be made that identifies any infant having a heritable or genetic disorder. ~~All medical records maintained as part of newborn screening services shall be confidential and shall be accessible only to the Board, the Commissioner, or his agents.~~

The Commissioner may authorize linkages between secure electronic data systems maintained by the Department of Health containing newborn screening records and the Virginia Immunization Information System (VIIS) operated pursuant to § 32.1-46.01. The Commissioner may authorize health care providers authorized to view VIIS to view the newborn screening records of individuals to whom the providers are providing health care services. The records may be made available until the child reaches seven years of age, after which the records shall not be made available through a linkage to VIIS. Such linkages shall be subject to all applicable state and federal privacy laws and regulations.