

Meeting Minutes
Periodic Review Regulatory Workgroup
Regulations Governing Newborn Screening Services
12 VAC 5-71

Wednesday, March 23, 2011
9:30 am-11:30 a.m.
Virginia Department of Health
109 Governor Street, 8th Floor
Richmond, Virginia

Attendance:

Willie Andrews	Division of Consolidated Laboratories
Joanne Boise	Virginia Department of Health
Lauren Bull	Virginia Department of Health
Britta Cedergren	March of Dimes
Lillie Chandler	Virginia Department of Health
Laura Duncan	VCU Health Systems
Tom Hickey	Division of Consolidated Laboratories
Jennifer MacDonald	Virginia Department of Health
Phil Poston	Division of Consolidated Laboratories
Susan Tlusty	Virginia Department of Health
Sharon Williams	Virginia Department of Health

The meeting was called to order at 9:35 a.m. No attendees participated by conference call although the call was open for 30 minutes.

Attendees at the meeting introduced themselves and their respective organizations.

Regulatory processes in Virginia were reviewed which included the steps involved in periodic review and proposing amendments to regulations.

The purpose of the periodic review and the criteria covered by the review were discussed.

Differences between the Code of Virginia, Virginia Administrative Code (regulations), and guidance documents were discussed.

No public comments were received regarding this periodic review.

The regulation was reviewed by section for comments.

Section 10: Definitions: Suggestions were made to change the reference from the Virginia Newborn Screening Services to Virginia Newborn Screening Program. It was also recommended to make this change throughout the document.

Section 20: Administration of chapter: This section may no longer be needed as the Registrar has deleted similar sections in other regulations.

Section 30: Core panel of heritable disorders and genetic diseases: The need to update the reference in subsection A from the *American College of Medical Genetics* to the *US Department of Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)*. The word "Detection" needs to be added to the reference for the newborn hearing screening program.

The Division of Consolidated Laboratory Services (DCLS) will provide an updated list to VDH for multiple changes to the uniform nomenclature and abbreviations developed for the listed newborn dried-blood-spot screened conditions.

Severe Combined Immunodeficiency (SCID) has been added to the Recommended Uniform Screening Panel of the SACHDNC as of May 2010. At this time the Virginia Newborn Screening subcommittee is in the planning phases of potentially adding SCID to the Virginia panel. Adding this disorder will require additional laboratory equipment to conduct DNA analyses and may require an increase in the filter paper charge. In addition, treatment for SCID requires a bone marrow transplant. An immunologist is being consulted to help Virginia's program understand the potential treatment requirements. At this time, the work group decided it would be premature to add SCID to the core panel as an implementation date has not been decided. It was questioned if Virginia could commence SCID screening prior to formally adding it to the list of conditions. It was noted that the regulation could be updated if and when a target implementation date was confirmed.

It was also discussed that after the expansion of newborn screening evolved across the country, it was discovered that the marker originally thought to detect Tyrosinemia type I (tyrosine) was not actually an indicator of that condition. This marker is actually an indicator of Tyrosinemia type II/type III. The marker that must be used to screen for Tyrosinemia type I (tyrosine) is succinyl acetone. The DCLS is not currently testing for this marker. To add this marker would require changes and the DCLS does not have a time frame for adding this marker. The laboratory is currently focused on the addition of DNA testing for cystic fibrosis which is one of the most common disorders diagnosed through newborn screening. It was decided to recommend removing Tyrosinemia type I from list of core panel disorders. It was recommended that Tyrosinemia type II/type III not be added to the core panel as they are reported out as secondary conditions resulting from testing conducted for core panel disorders. It was also noted that this decision is consistent with what some other states have done.

Section 40: Religious exemption from newborn dried-blood-spot screening requirements: No changes were recommended for this section.

Section 50: Responsibilities of the physician or midwife: No changes were recommended for this section.

Section 60: Responsibilities of the first attending healthcare provider: No changes were recommended for this section.

Section 70: Newborn dried-blood-spot screening specimen collection, specimen submission, and notification for hospital deliveries: No changes were recommended for this section. Although there has been some discussion of how to handle screening for neonatal intensive care unit cases, no formal protocols have been developed at this time.

Section 80: Newborn dried-blood-spot screening specimen collection, specimen submission, and notification for deliveries outside of the hospital: No changes were recommended for this section.

Section 90: Responsibilities of the chief executive officer: No changes were recommended for this section.

Section 100: Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests: No changes were recommended for this section.

Section 110: Reporting to the commissioner: No changes were recommended for this section.

Section 120: Scope and content of Virginia Newborn Screening Services: Changes were recommended to update references from "services" to "program". There was some discussion of performance measures, however, it was recommended to leave the current text as is.

Section 130: Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network: Changes were recommended to update references from "services" to "program".

Section 140: Responsibilities of metabolic treatment and genetic centers facilities: Changes were recommended to update references from "services" to "program".

Section 150: Responsibilities of the Care Connection for Children network: Changes were recommended to update references from "services" to "program".

Section 160: Availability of assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements: No changes were recommended for this section.

Section 170: Emergency suspension of assistance: Changes were recommended to update references from "services" to "program".

Section 180: Use of federal, state, or other resources: Changes were recommended to update references from "services" to "program".

Section 190: Confidentiality of information: Changes were recommended to update references from "services" to "program".

No other additional sections or modifications were proposed by the group.

The meeting was concluded.