

Regulatory Advisory Panel  
12 VAC 5-71  
Regulations Governing Virginia Newborn Screening Services

Meeting  
October 24, 2012  
10 am  
Virginia Department of Health  
109 Governor Street  
Richmond, Virginia 23219

Attendance:

Virginia Department of Health Staff:

Cathy Cornelius, RN, Public Health Nurse, Virginia Newborn Screening, Office of Family Health Services  
Kathleen Moline, RN, BSN, MA, Virginia Newborn Screening Supervisor, Office of Family Health Services  
Susan Tlusty, Division of Policy and Evaluation, Office of Family Health Services

Regulatory Advisory Panel Members:

Nikki Downs, Director of Birthing and Family Health Services, Riverside Health System

*By-phone:*

Oral Alpan, M.D., Chief, Section on Immunopathogenesis, O & O ALPAN, LLC  
Wanda Andrews, BSMT (ASCP), Director, Laboratory Operations, Division of Consolidated Laboratory Services  
Barb Ballard, Parent and Patient Advocate, Board of Trustees The Immune Deficiency Foundation  
Tom Hickey, PhD, DABCC, Division of Consolidated Laboratory Services  
Susan Ward, Vice President and General Counsel, Virginia Hospital & Healthcare Association  
Tom York, Division of Consolidated Laboratory Services

Group members introduced themselves and their organizations represented. The function of the Regulatory Advisory Panel and their role to provide advice and input during the regulatory action development for the potential addition of Severe Combined Immunodeficiency (SCID) to the current core panel for which every newborn in Virginia is screened was discussed. These conditions are listed in 12 VAC 5-71 Section 30. This action is being initiated following recommendations from the Virginia Genetics Advisory Committee and the recent September 20-21 meeting of the Virginia SCID Planning Workgroup. The group was informed that recommendations go through senior VDH management, the Board of Health, and Executive Review and may change at any time throughout that process. The standard regulatory process was reviewed and participants were directed to the Virginia Regulatory Town Hall website for further details. In addition, the more comprehensive work required at the proposed stage analysis was discussed. The opportunities for public comment at each stage were also reviewed. Requirements for Virginia Newborn Screening Services under the Code of Virginia were briefly reviewed.

The group commented on the preliminary draft text for the Notice of Intended Regulatory Actions. Corrections were suggested for the overall number of conditions on the national recommended panel due to counting Critical Congenital Heart Disease (CCHD) and newborn hearing screening. Recommendations were discussed to add brief information about DNA testing and technology; how newborn screening fees are currently levied and paid; and statements regarding the excess morbidity

and costs associated with undiagnosed infants. Panel members agreed to send VDH statements regarding these issues relative to their areas of expertise and interest.

The group was informed that updates to the NOIRA process would be shared via email. The next meeting will be scheduled following public comment on the NOIRA.

The entire meeting may be heard through November 30, 2012 at:

<http://www2.eintercall.com/moderator/presentation/Playback?id=de3ef936-0a63-4344-8c1d-5e19e3326ff8.rpm>