Economic Impact Analysis
Virginia Department of Planning and Budget

12 VAC 5-71 –Regulations Governing Virginia Newborn Screening Services
Virginia Department of Health
May 9, 2006

Summary of the Proposed Regulation

The proposed regulations expand the panel of diseases newborns are screened for from 12 to 29. In addition, the proposed amendments establish an income eligibility criterion for publicly provided formula and food benefits and clarify the roles and responsibilities of different entities involved in the newborn screening. The proposed permanent regulations have been in effect since March 1, 2006 under emergency regulations.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

These regulations establish rules for the newborn screening services in the Commonwealth. The main goal of newborn screening is to test and find out as early as possible whether a baby has certain health problems. The screening is conducted on a few drops of blood from the baby's heel collected on a special test paper. The test paper is purchased by the hospital, birthing center, or health care provider at a cost of $53 from the Division of Consolidated Laboratory Services within the Department of General Services. Blood samples, once collected, can be used to screen for many different disorders. In some cases, the tests have to be repeated if the blood sample is not taken after the first 24 hours following birth or the sample is contaminated.

Once elevated levels of disease indicators are found in a sample, a follow up process is initiated by the Department of Health toward a diagnosis and treatment. Screening services includes expert consultation on abnormal results, diagnostic testing, nursing follow up, medical and dietary treatment, and assistance with the purchase of special formulas and low protein

foods. These disorders if not treated can lead to slow growth, severe illness, brain damage, or possibly death. Early diagnosis helps prevent serious health problems later in the life while affording the baby the best chance to grow and develop normally.

One of the proposed changes increases the number of heritable and genetic diseases that are screened from 12 to 29. With the proposed changes, the Commonwealth now screens for argininosuccinic acidemia, beta-ketothiolase deficiency, biotinidase deficiency, carnitine uptake defect, citrullinemia, congenital adrenal hyperplasia, congenital hypothyroidism, cystic fibrosis, galactosemia, glutaric acidemia type I, hemoglobin sickle/beta-thalassemia, hemoglobin sickle/c disease, homocystinuria, isovaleric acidemia, long chain hydroxyacyl-CoA dehydrogenase deficiency, maple syrup urine disease, medium-chain acyl-CoA dehydrogenase deficiency, methylmalonic acidemia (mutase deficiency), methylmalonic acidemia, multiple carboxylase deficiency, phenylketonuria, propionic acidemia, sickle cell anemia (Hb SS disease), tyrosinemia type I, trifunctional protein deficiency, very long-chain acyl-CoA dehydrogenase deficiency, 3-hydroxy 3-methyl glutaric aciduria, and methylcrotonyl-CoA carboxylase deficiency. The screening for these disorders is recommended by the American College of Medical Genetics.

These diseases are targeted for screening because advances in technology made it relatively easy to identify abnormal samples. The technology known as “tandem mass spectrometry” makes it possible to screen for all of these diseases using a single dried blood spot. The other characteristic common to these diseases is that there are available treatments for them. Thus, screening leads to early diagnosis which can lead to early treatment and prevention or minimization of significant morbidity or mortality.

The proposed regulations also require that all diagnosed children be referred to Care Connection for Children. Care Connection for Children provides follow up services such as case management.

Increasing the number of diseases screened from 12 to 29 is estimated to increase the number of metabolic disorder diagnoses by 18 new cases and cystic fibrosis diagnoses by 28 new cases based on the national prevalence estimates. The diagnoses of additional cases are likely to increase the costs. The potential increase in costs to the Commonwealth is estimated at $586,000. Of this amount, approximately $108,000 is for 1.5 FTE RN position and 0.66 FTE support staff to conduct daily follow up of abnormal results and the administration of the food/formula

program. Approximately $45,000 is for educating medical providers about the expanded panel of diseases, development of materials, and other training. Approximately $45,000 is for developing and modifying the existing data reporting systems. Another $218,000 is anticipated for the costs of contracting with healthcare providers for consulting on abnormal test results and diagnostic testing and long-term medical management. Approximately $85,000 is estimated for the purchase of special metabolic formulas and low protein modified formulas to be used in the treatment of diagnosed disorders. Finally, approximately $85,000 is estimated for 3 FTE positions that will be working at six regional Care Connection Centers for children to facilitate case management and support.

In practice, a large portion of costs to administer the newborn screening services is financed by the fees collected from hospitals and birthing centers for the test filter paper. The fee is established by the Division of Consolidated Laboratories of the Department of General Services in consultation with VDH. The fee is increased to $53 in November 2005 from $32 in order to cover the expected increase in the costs to administer the program. Even though the increase in the fee is not specified in the proposed regulations, the recent increase in the fees practically shifts the additional costs of the proposed regulations onto the hospitals and birthing centers. Moreover, the training for the testing of additional panel of diseases may increase the costs slightly.

Despite the additional costs, the proposed changes are expected to produce net benefits for the Commonwealth. Available evidence suggests that screening is cost effective. According to VDH, a research done by the State of Wisconsin indicates every four dollars spent on screening provides five dollars savings in avoided costs. This suggests that we should expect net benefits from the proposed expanded panel of diseases. However, the actual size of benefits is subject to many case specific factors. The number of diseases actually diagnosed, the type of the diseases diagnosed, the response to treatment are just a few factors to name. These savings could accrue to health care providers, insurance companies, families of newborns, newborns themselves, and the Commonwealth of Virginia. Additionally, the children who are diagnosed and treated avoid poor prognosis and the need for medical and assistive care. Finally, diagnosis of one of these conditions informs parents about a possibility of a genetic disorder and allows them to make informed decisions about future reproductive decisions.

The proposed changes also remove language regarding the amount of formula and food program benefits available. For the special formulas, the code of Virginia (§ 32.1-67) stipulated that VDH reimburse the families for the costs of special formula up to 2% of their income. For the special foods, the statue stipulated that reimbursements be capped at $2,000 per diagnosed person per year. Effective March 2006, these statutory requirements were removed from the code of Virginia. With the proposed changes, VDH is making special formula and food benefits available at no charge to individuals with income levels below 300% of federal poverty level. The cap for special food reimbursements is reduced to $1,500. Also, VDH is making special formulas and foods available for purchase at cost for those with incomes above 300% of federal poverty level. Finally, the financial assistance is expanded to cover other services such as medication, hospitalizations, nutritional supplements, and durable medical equipment.

The proposed changes to the eligibility criteria bring consistency in different types of public assistance made available through the Pool of Funds improving the equitability among families in need. Individuals with incomes above 300% FPL will no longer be able to receive free public benefits, but may purchase special formula and foods at cost from VDH. Additionally, the reduced cap of $1,500 reimbursement for special foods is likely to increase the out of pocked expenditures up to $500 for some recipients. According to VDH, of the 28 families using this benefit, 12 would qualify, 12 would not qualify under the proposed rules. The income information for the remaining four families is not available to determine whether they would qualify or not.

Finally, the proposed regulations specify the roles and responsibilities of hospitals, primary care providers, and testing laboratory. With these proposed changes, the clarity of the responsibilities of parties involved in administering the screening program is improved. The proposed clarifications should strengthen the enforceability of the proposed regulations, improve the uniformity of the standards across Virginia, and improve the chances of a newborn receiving treatment in a timely manner. Usually, the timing of the treatment is a critical element in the success of the treatment applied.

Businesses and Entities Affected

Approximately 101,000 infants born each year in the Commonwealth will be screened for an expanded panel of diseases. The specimens are collected by approximately 65 hospitals and

birthing centers. The number of licensed physicians and midwives who provide healthcare for the infants is estimated to be approximately 3,800.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment

The proposed regulations may slightly increase the demand for labor due to the additional labor that may be required to test for expanded panel of diseases and are estimated to increase the demand for labor due to the anticipated increase in the diagnosis of more cases. Some of the expected increase in demand for labor may be offset by the incentives to reduce capacity as result of the increased fee.

Effects on the Use and Value of Private Property

The proposed regulations are primarily responsible for the fee increase and could necessitate training and consequently are expected to reduce the profitability of the private hospitals and birthing centers which would reduce the asset value of these businesses. Also, the diagnosis of additional disorders may increase or decrease the revenues and the asset values of these hospitals, birthing centers, and other related businesses depending on whether or not they are compensated for the services.

Small Businesses: Costs and Other Effects

The main effects of the proposed regulations are expected to be on the hospitals and birthing centers and not so much on the licensed physicians and midwives that could be considered as small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact

The proposed regulations are not expected to have a significant effect on small businesses.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.H requires that such economic impact

analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.