



TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF LABORATORY SERVICES

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PUBLIC HEALTH LABORATORY DIRECTOR

LISA PIERCEY, MD, MBA, FAAP
COMMISSIONER

TO: Dr. Lisa Piercey, MD, MBA, FAAP
FROM: Richard Steece, PhD, D (ABMM)
DATE: August 2, 2019
SUBJECT: 2020 Newborn Screening Fee Increase

Handwritten signatures in blue ink. The signature for Lisa Piercey is larger and more prominent, while the signature for Richard Steece is smaller and positioned below it.

Spinal Muscular Atrophy (SMA) is a disease resulting in the deterioration of motor neurons resulting in progressive muscle weakness and wasting. More severe forms of SMA affect the muscles for feeding, swallowing, and breathing thereby making SMA the number one genetic cause of death for infants. Hence, early detection of SMA provides the opportunity for treatment and disease management with new drugs such as Spinraza (Nusinersen) and gene therapy.

In 2018, our genetic advisory committee recommended the addition of SMA to the Tennessee panel harmonizing with the national Recommended Uniform Screening Panel (RUSP). The RUSP is a listing of disorders for which all infants born in the United States should be screened and is published by the Advisory Committee on Heritable Disorders in Newborn and Children (ACHDNC) in conjunction with the Department of Health and Human Services (HHS). Very shortly, the Tennessee newborn screening laboratory will begin a validation study for SMA with hopes to begin routine screening of all Tennessee newborns prior to or on January 1, 2020. However, to remain current with the RUSP and to offer Tennessee babies the best service possible comes with a cost.

To fund the SMA screen and any additional testing related to SMA, and provide appropriate follow-up services, the current fee of \$145 will need to increase to \$165. We are asking that this increase go into effect for all newborn screening samples received beginning on January 1, 2020. The fee will cover the addition of SMA, second tier SMN copy number testing, and our current panel of 70 disorders. It will also cover the following: sustained weekend work to cover 7 day a week testing to improve timeliness of reporting, sustained courier system, purchase a specimen tracking and electronic demographic transfer and reporting system, and expansion of the newborn screening laboratory to accommodate the addition of new disorders. The fee for unsatisfactory samples will also change from \$290 to \$310. This fee covers the first unsatisfactory submission and any additional repeat specimen submissions.

We anticipate your favorable response to this fee increase.