June 17, 2020

Robert Myers, Ph.D.
Director, Maryland Public Health Laboratory Division
Maryland Department of Health
1770 Ashland Avenue
Baltimore, MD 21205

Dear Dr. Myers,

On behalf of the 550 people living with cystic fibrosis (CF), we appreciate all that the Maryland Department of Health Laboratories Administration does for people with CF and the critical role that your department plays in the early detection and treatment of the disease. While we understand the challenges caused by the COVID-19 pandemic, it is more important than ever that Maryland implement IRT/DNA testing for its newborn screening processes as soon as possible to ensure early detection of cystic fibrosis in infants.

As you know, CF is caused by genetic mutations that result in the malfunction of a protein called the cystic fibrosis transmembrane conductance regulator (CFTR). Decreased CFTR function causes irreversible damage and the associated symptoms of cystic fibrosis that lead to early death, usually by respiratory failure. As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high-quality, specialized CF care, the Cystic Fibrosis Foundation accredits more than 130 care centers nationally—including four in Maryland—that provide multidisciplinary, care in accordance with systematically-reviewed, data-driven clinical practice guidelines.

By diagnosing CF early, CF health care providers can help parents learn ways to keep their child as healthy as possible and delay or prevent serious, lifelong health problems related to CF. Research shows that children who receive CF care early in life have better nutrition and are healthier than those who are diagnosed later. Early diagnosis and treatment can help improve growth, help keep lungs healthy, reduce hospital stays, and add years of life expectancy for people with CF.

We are concerned that the IRT/IRT newborn screening methodology employed by the state of Maryland is prone to lower sensitivity and preventable delays in diagnosis and urge the Laboratory Administration to transition to a CFTR/DNA-based algorithm, as has occurred in all other 50 states, as soon as possible. Data from a variety of studies show that delays in diagnosis often lead to irreversible malnutrition and other suffering. Thus, avoiding delays and missed cases has become increasingly important in this era of preventive therapies for CF. In addition, the opportunities for genetic counseling after IRA/DNA screening have enhanced CF newborn screening elsewhere.

We ask the state of Maryland provide an anticipated timeline for implementation of CFTR/DNA newborn screening procedures and inform us of the steps necessary to ensure this occurs. The Cystic Fibrosis

Foundation stands ready to assist the Division of Newborn and Childhood Screening with its transition to IRT/DNA analyses however we can. Should you have any questions regarding our request, please contact Sarah Webster-Mellon, State Policy Manager, at swebster-mellon@cff.org or (610) 322-7534. We thank you for all you do for people with cystic fibrosis.

Sincerely,

Bruce C. Marshall, MD
Chief Medical Officer
Executive Vice President of Clinical Affairs

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Chief Policy & Advocacy Officer
Senior Vice President of Policy and Advocacy

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