American
Clinical Laboratory
Association

September 27, 2018

Ms. Kathy Stiffler
Acting Deputy Director, Medical Services
Michigan Department of Health and Human Services
333 S. Grand Avenue
P.O. Box 30195
Lansing, Michigan 48909

Dear Ms. Stiffler,

The American Clinical Laboratory Association (ACLA) strongly disagrees with the Michigan Medicaid program's determination earlier this year that it no longer would cover prenatal carrier screening for cystic fibrosis (CF), and we urge the program to reverse course and continue covering this screening. ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs more than 6,000 people in Michigan and generates over 2,700 additional jobs in supplier industries in the state.

CF is a serious multisystem disease that affects the pulmonary, pancreatic, and gastrointestinal systems, and respiratory failure is the most common cause of death among those with the disease. The disease incidence is approximately 1 in 2,500 individuals in the non-Hispanic white population meaning that 1 in every 25 individuals in the population is a carrier of cystic fibrosis. The average life expectancy of an individual with CF is 42 years.

Prenatal carrier screening for CF has been the standard of care in the United States since at least 2001. In 2005, the American College of Obstetricians and Gynecologists (ACOG), which provides reliable, science-based guidance to women's healthcare providers, recommended offering CF carrier screening to all women who are considering pregnancy or currently are pregnant, and this recommendation has been reaffirmed several times since then. ACOG also recommends that if a woman has been determined to be a CF carrier, her male partner should be tested, because when two CF carriers have a child, there is a 1 in 4 chance that the child will have CF.[1]

We understand that the Office of Medical Affairs has said that since a CF screening test is standard for newborns, prenatal testing "may be redundant". ACLA agrees with ACOG that newborn screening panels do not and should not replace prenatal carrier screening, and they do not diminish the value of carrier screening.

ACLA also takes issue with the notion that prenatal testing does not affect prenatal care for the Medicaid beneficiary. A study published in the *American Journal of Respiratory and Critical Care Medicine* revealed that by the time newborn screening results in a diagnosis of CF, a substantial portion of asymptomatic infants with CF already have lung disease with bacterial

[1] *See* Carrier Screening for Genetic Conditions, Committee Opinion No. 691, American College of Obstetricians and Gynecologists (March 2017), *available at* https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co690.pdf?dmc=1&ts=20170718T0046152351.

infection, bronchial dilation, and inflammation.[2] A 2009 article in the journal *Current Opinion in Pulmonary Medicine* cites growing evidence that CF lung damage starts early in life and may be present by the time of diagnosis by newborn screening at four to six weeks of age.[3] This suggests that there may be a benefit to identifying neonates at high-risk of having CF because newborn screening results may not be available for several weeks and interventions and treatments therefore can be delayed. A Medicaid beneficiary who is carrying a child at high risk of CF can arrange for immediate interventions for her child. In short, while Michigan Medicaid covers CF testing "for beneficiaries when clinical symptoms indicate a need for testing," it may be too late.

Many private payors and state Medicaid programs cover prenatal carrier screening because they have recognized the value of the screening prior to pregnancy or early in a pregnancy for couples. They also recognize that a child with CF who is born to a Medicaid beneficiary becomes a Medicaid beneficiary at birth, and it makes good sense to address this serious disease immediately. We respectfully request that you reconsider your decision and continue covering prenatal CF carrier screening. ACLA and its members welcome the opportunity to discuss this with you as soon as possible.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs

[2] Sly PD *et al*. Lung diseases at diagnosis in infants with cystic fibrosis detected by newborn screening. Am. J. Respir. Crit. Care Med. 2009; 180: 146-152.
[3] Stick SM. The first 2 years of life: implications of recent findings. Curr. Opin. Pulm. Med. 2009; 15: 615-620.