Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

March 16, 2022

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East Miller Office Building
Annapolis, MD 21401-1991

Re: SB 883 – Public Health – Sickle Cell Disease – Testing at a Community-Based Health Fair - Letter of Information

Dear Chair Kelley and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of information for Senate Bill (SB) 883 - Public Health – Sickle Cell Disease – Testing at a Community-Based Health Fair. SB 883 requires MDH to authorize qualified individuals to offer and perform laboratory testing for detecting sickle cell disease at community-based health fairs.

Under Md. Code Ann. Health-General, § 13-111, MDH's Laboratories Administration Division of Newborn and Childhood Screening is mandated to conduct hereditary and congenital screening for all infants born in the State of Maryland. Infants are screened for approximately 61 primary and secondary known disorders to determine those at risk for particular disorders and those who may need additional diagnostic testing. This screening includes sickle cell trait and disease testing.

Additionally, MDH provided testing services for sickle cell in adults through 2019. However, the testing services stopped because MDH only received a few specimens per year. In fact, only eight (8) specimens were received for testing in 2018 and three (3) were received in 2019. Therefore, the cost to maintain the equipment/instruments, reagents, and supplies was considerable in comparison to the total number of specimens received for adult sickle cell testing.

Lastly, MDH is not aware of any U.S. Food and Drug Administration (FDA) approved Clinical Laboratory Improvement Amendments (CLIA) waived tests for sickle cell that can be used at community-based health fairs.[1] Screening for sickle cell has been designated by the FDA as a high complexity test and as such, Maryland cannot waive the federal requirement for this level of testing to be performed in a CLIA certified high complexity lab. If SB 883 is enacted, samples

[1] The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 260,000 laboratory entities.

will need to be collected at community-based health fairs in compliance with CLIA regulations and forwarded to MDH for testing. In order to reinstate adult sickle cell testing in the MDH lab, additional staff, equipment, reagents and supplies for testing and follow-up services on positive screening results will be required.

If you have any questions or need additional information, please feel free to contact Ms. Heather Shek, Director of the Office of Governmental Affairs at heather.shek@maryland.gov or (410) 260-3190.

Sincerely,

Dennis R. Schrader
Secretary