March 8, 2022

The Honorable Shane E. Pendergrass, Chair House Health and Government Operations Committee House Office Building, Room 241 Annapolis, MD 21401-1991

RE: HB 1266 – Dentists - Saliva Lead Poisoning Screening Tests - Scope of Practice and Requirements – Letter of Information

Dear Chair Pendergrass and Committee Members:

The Maryland Department of Health (MDH) and the Maryland Department of the Environment (MDE) jointly submit this letter of information for House Bill 1266 – "Dentists - Saliva Lead Poisoning Screening Tests - Scope of Practice and Requirements." This bill would authorize a dentist to collect a sample of saliva and send it to a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory to be tested for lead. It would also require the dentist to send the results of the test to the parent or legal guardian of the child and to report the results to MDE.

No national health agency or organization involved in lead poisoning prevention (including the U.S. Centers for Disease Control and Prevention and the American Academy of Pediatrics) has provided guidance related to saliva lead testing. MDH's review of the medical literature notes a few articles investigating the possible use of saliva lead as a screening test in children. However, a 2015 review of the topic of saliva screening tests concluded that, "...The literature survey on lead in saliva—and more specifically correlation of saliva lead to serum- or blood- lead concentrations—is quite contradictory." Currently, MDH requires primary care providers to test blood lead levels in all children at 12 and 24 months of age. Unlike saliva tests, blood lead level tests are clinically validated and provide parents and primary care providers with actionable information.

MDH acknowledges that there is at least one peer-reviewed published report showing that a saliva lead test would not incorrectly identify children with blood lead levels of 5 micrograms/deciliter or greater as having "no lead exposure" (the predictive value of a negative saliva test). However, MDH bases its recommendations and regulations on tests that have been thoroughly evaluated through the consensus of national bodies and believes it is premature to adopt a saliva lead test in statute. This is even more important now that the CDC has adopted a new, lower Blood Lead Reference Value (BLRV) of 3.5 micrograms/deciliter, which Maryland has also recommended to clinicians as the BLRV for clinical follow-up. The data from the one publication noted above did not specifically address the ability of a salivary test to accurately distinguish positive and negative tests with a BLRV of 3.5 micrograms/deciliter, so the Department was unable to find any substantiation for the use of this test.

¹ Michalke B. *Saliva as a matrix for human biomonitoring in occupational and environmental medicine*. Int Arch Occup Environ Health. 2015 Jan; 88(1):1-44. doi: 10.1007/s00420-014-0938-5. Epub 2014 Mar 12.

² Gardner SL, et al. *Evaluating Oral Fluid as a Screening Tool for Lead Poisoning*. Journal of Analytical Toxicology (November, 2016); 40(9):744-748. Available at: https://academic.oup.com/jat/article/40/9/744/2527450.

³ See Maryland Department of Health Provider Letter of January 25, 2022.

The Departments also note that Environment Article §6-303 requires "A medical laboratory, office, or other facility that draws blood from any child 18 years and under for analysis of blood lead levels..." to report the results of that blood lead test to MDE. The proposed legislation would not, as written, alter the requirements in the Environment article and would, in the opinion of MDH, not pertain to saliva lead testing.

The proposed legislation does not alter the current requirements for blood lead testing in Maryland law and regulation. A positive saliva lead test might lead some parents to consider blood lead testing if their child has a positive saliva lead test. However, the Departments are also concerned that parents may view the results of a negative saliva lead test as evidence that a blood lead test is not necessary. In addition, positive saliva lead tests will have to be confirmed by a blood lead test because there are insufficient data and validation studies to predict the blood lead level from a saliva lead test.

Finally, dentists generally have not received training in providing the kind of counseling and medical follow-up required in the event of a test showing a possibly elevated lead level, particularly since there is no national guidance on the interpretation of saliva lead test results. For example in CY 2019, 408,862 children 0-20 enrolled in Medicaid received a preventive or diagnostic dental service. For children ages 0-2 years old, 10.4% of those who accessed dental services had not had a lead test performed. Assuming a similar percentage of children ages 0-20 accessing dental services received a lead screening, MDH estimates that 42,522 children would receive a lead screening under HB 921. MDH assumes that it would cost \$2 per actual saliva test device, \$13 for a dentist to perform a lead saliva screening on a child, \$5 for shipping and storage, and \$45 for that saliva to be processed by a lab, totaling \$65 per lead screening. The total cost of dentists performing lead tests on Medicaid-eligible children would be \$2.6 million per year.

I hope this information is useful. If you would like to discuss this further, please contact MDH Director of Governmental Affairs Heather Shek at (410) 260-3190 or heather.shek@maryland.gov or MDE Chief of Staff Tyler Abbott at tyler.abbott@maryland.gov or (410) 537-3537.

Sincerely,

Dennis R. Schrader Secretary of Health

Jamis P. Shodan

Ben Grumbles

Secretary of the Environment

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