Amendments we support for HB 1625

Page and Line #s	Amendment language	Intent
P. 3, Line 7	"(e) (1) (i) The Department shall screen for: 1. Each core condition listed in the US Department of Health and Human Services' Recommended Uniform screening Panel as of May 31, 2026. 2. Each condition that is not on the RUSP but meets at least these criteria, as notified by the Maryland Rare Disease Advisory Council: A. There is a newborn screening assay available, and B. There is an FDA approved treatment. (e) (1) (ii) The Department shall set a review schedule by December 31, 2026, and implement screening by December 31, 2028, the following conditions that meet the above criteria: 1. Sanfilippo syndrome type A (MPS IIIA) 2. Morquio syndrome type A (MPS IVA) 3. Maroteaux-Lamy syndrome (MPS VI) 4. Sly syndrome (MPS VII) 5. Batten disease type 2 (CLN2) 6. acid sphingomyelinase deficiency (ASMD) (e) (1) (iii) Determine an ongoing process for the Department to coordinate with the Maryland Rare Disease Advisory Council in identification and notification of conditions that meet these criteria, and notifying the Advisory Council within 3 months of both criteria being met. The conditions will be implemented within 2 years of notification to the Advisory Council and otherwise follow the same timelines and processes as RUSP approved conditions.	The intent is to set up the minimal criteria to consider adding "non-RUSP" conditions, which conditions currently meet those criteria, and establish a way to keep identifying those conditions in a timely manner going forward. The list of conditions here was carefully chosen so as not to overwhelm the lab. This is a group of conditions all known as Lysosomal Storage Disorders that are all on testing kits that the lab either has or can obtain (Revvity and Enfanos are the newborn screening assay development companies). The one exception is Sanfilippo Syndrome – this condition currently has an available NBS assay, and a treatment is under FDA review (their decision is anticipated this year, hence it is included). Clearly this is meant to continue on with other conditions over time. Regs should be written to accomplish that. For now, we're suggesting the Department should set a schedule by year's end for this list to be reviewed and conditions that are approved should be added by 12/31/28. The rest of the bill's language and its timelines will apply to both RUSP conditions and "non-RUSP" conditions. You'll see the reference to Maryland Rare Disease Advisory Council here. This is the body that could be continuously horizon scanning for conditions that meet these criteria. They could coordinate with the Department on schedule of notification (i.e. quarterly, biannually), and defining the criteria.
P. 3, Line 13	"is added to the Recommended Uniform Screen Panel, or if a condition is not on the RUSP but has met the non-RUSP review criteria, the Advisory Council shall:	Given that the federal committee that reviews conditions has been terminated by the federal government, the state of MD should be able to also contemplate adding "non-RUSP" conditions. However, there needs to be criteria set that will ensure that the state need only review state level elements of the condition. The state should not be compelled to do an ACHDNC-equivalent review. For example, the state should not need to review whether or not a newborn screening assay works in state labs across the US (the state can review only that it works in Maryland's lab), so the criteria of "there is an available newborn screening assay" means that is already a proven element.

		Another example, the criteria of "there is an FDA approved treatment" means that the condition is treatable. The state's review should be only on the elements to do with the state's ability to screen for the condition according to the state's requirements (typically set by the state Advisory Council.
P. 3, Line 16	"…accessibility, the benefits to individuals, families, and the rare disease community of early identification of the condition, and costs of implementing testing for the condition	There is potential cost savings to the State and health care system associated with early diagnosis, including the avoidance of diagnostic odysseys, preventable hospitalizations, intensive care utilization and long-term disability, not to mention parents' ability to work and continue to be productive citizens.
P. 3, Line 19	Delete "If a core condition is added to the Recommended Uniform Screening Panel," and start that sentence with "The Department may…"	Removing this phrase makes everything under it applicable to any condition the Advisory Council is reviewing whether it's RUSP approved or not.
	Remove the word "core" throughout the document except for on Page 3 Line 7.	"Core" is a reference to the RUSP which is organized into core and secondary conditions. The RUSP rarely if ever adds secondary conditions, so there is no need to specify "core." Also removing the word "core" throughout allows any reference to "condition" to be applicable to RUSP and "non-RUSP" conditions.
P. 3, Line 30	"…Screening Panel, or is not on the RUSP but the Advisory Council has been notified that a condition meets the non-RUSP review criteria, due to a delay in the procurement,…"	
P. 3, Line 34	"condition to the Recommended Uniform Screening Panel, or is not on the RUSP but the Advisory Council has been notified that a condition meets the non-RUSP review criteria, and every 3 months thereafter	
P. 4, Line 2	*Delete the last word "for"*	
P. 4, Line 3	"beyond" *delete "a period of more than"* "the 2 years deadline," the Department shall report to the	
P. 4, Line 7	"Recommended Uniform Screening Panel, or is not on the RUSP but the Advisory Council has been notified that a condition meets the non-RUSP review criteria,.	
P. 4, Line 14	"implementation of testing, required information for reevaluation, and the anticipated timeline for implementation	This is meant to inform rare communities what would be needed in order to have the condition reevaluated – a transparency component.