Dear Commissioner Cunningham,

In anticipation of the federal Recommended Uniform Screening Panel (RUSP) expanding, the newborn screening lab and follow up teams have been preparing and assessing readiness for adding new RUSP-approved conditions. The RUSP is a list provided from the Secretary of Health and Human Services containing disorders states should aim to add to their newborn screening panels. RUSP-approved conditions undergo a thorough review process through the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) to assess factors including states' overall readiness to implement screening, net benefit of screening, public health impact, and availability of effective treatment among others. The ACHDNC created a report for the Evidence Review they conducted for each condition. Advisors were provided with this evidence review and asked to review it prior to the June 6, 2023 meeting.

Minnesota has largely been up to date with screening for RUSP-approved conditions, however, two new conditions have been reviewed and added to the RUSP this past year: mucopolysaccharidosis type II (MPS II) and guanidinoacetate methyltransferase (GAMT) deficiency.

On October 4, 2022, Amy Hietala (lab supervisor) and Sondra Rosendahl (follow up supervisor) presented to the Advisory Committee on Heritable and Congenital Disorders (also known as the Newborn Screening Advisory Committee) on the Minnesota Newborn Screening Program's readiness and approach to screening for MPS II and GAMT deficiency. MPS II was added to the RUSP in August 2022 and GAMT deficiency was added in January 2023. Sondra Rosendahl also presented to the committee at the June 6, 2023 meeting about the status of these conditions.

A few key elements of the discussion are highlighted below:

- No need for new equipment or additional lab staff due to ability to multiplex with another test for both conditions.
- Second tier testing is available through an existing contract with Mayo Clinic Laboratories for MPS II to help reduce the number of false positives. No second tier needed to screen for GAMT deficiency.
- Additional follow up staff is not needed since the expected case load for both conditions combined is less than 20 per year based on prevalence and screening approach.
- Those who screen positive will be referred to our already established metabolic clinics for follow-up.

Following discussion, the Committee elected to proceed with a vote on the following:

Do you recommend that the Commissioner of Health add guanidinoacetate methyltransferase deficiency (GAMT) to the Minnesota Newborn Screening panel?

No, it is not ready for addition at this time = 2

Yes, I recommend its addition = 14

Do you recommend that the Commissioner of Health add mucopolysaccharidosis type 2 (MPS II) to the Minnesota Newborn Screening panel?

No, it is not ready for addition at this time = 0
Yes, I recommend its addition = 15
Members abstaining from vote = 1

With a majority vote, the Committee has recommended the addition of GAMT and MPS II to Minnesota's newborn screening panel.

Thank you for your consideration in approving this recommendation.

Sincerely,

/s/

Rae Blaylark, Chairperson