DEPARTMENT OF HEALTH

memo

| DATE: | January 26, 2022 |
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| TO: | Commissioner Jan Malcolm |
| THROUGH: | Dan Huff, Assistant Commissioner, Health Protection Bureau |
| | Myra Kunas, Director, Public Health Laboratory Division |
| | Sara Vetter, Assistant Director, Public Health Laboratory Division |
| FROM: | Jan Larson, Chair, Advisory Committee on Heritable and Congenital Disorders |
| | Rae Blaylark, Vice Chair, Advisory Committee on Heritable and Congenital Disorders |
| | Sondra Rosendahl, Interim Follow-up Supervisor/Committee Coordinator, Newborn Screening, Public Health Laboratory |
| | Mark McCann, Manager, Newborn Screening, Public Health Laboratory |

SUBJECT: Request for response on the recommendation made by the Advisory Committee on Heritable and Congenital Disorders (also called the Newborn Screening Advisory Committee)

The Minnesota Advisory Committee on Heritable and Congenital Disorders would like you to consider the expansion of the Minnesota newborn screening panel to include congenital cytomegalovirus (cCMV).

The mechanism for revising the list is described in Minnesota Statute, 144.125 "Tests of infants for heritable and congenital disorders," as follows:

"The list of tests to be performed may be revised if the changes are recommended by the advisory committee established under section 144.1255, if approved by the commissioner, and published in the State Register. The revision is exempt from the rulemaking requirements in chapter 14, and sections 14.385 and 14.386 do not apply."

At the January 11, 2022 Advisory Committee meeting, members voted 16:3 to recommend the addition of cCMV to Minnesota's newborn screening panel. Committee members understood that implementation would require MDH to secure resources (including hiring and training staff, purchasing equipment, making laboratory space accommodations), establish follow-up protocols, make changes to laboratory information management systems, develop education plans, and coordinate other necessary implementation efforts. In addition, committee members understood the legal and political efforts in Minnesota surrounding the Vivian Act, which prompted the review of this condition for possible addition.

On the national level, although some states are performing targeted screening for cCMV, it is <u>not</u> one of the conditions on the recommended uniform screening panel (RUSP). The addition of cCMV to Minnesota's newborn screening panel would make Minnesota the first in the country to screen for this condition universally.

At this time, we are asking you to review the Advisory Committee's recommendation to add cCMV to Minnesota's newborn screening panel. The enclosed documentation includes information provided to committee members and highlights the benefits and risks of screening for cCMV. We are also seeking approval for the draft language for our future submission to the State Register. We hope you find this package helpful as you thoughtfully consider this recommendation.

If these are satisfactory, we ask that you sign and date this page to indicate your decision.

With regards to the Committee's recommendation to add cCMV to the screening panel:

___X__ I approve this addition and the submission to the State Register

_____I decline this addition

/s/

Jan K. Malcolm, Commissioner of Health

Date

ENCL: Chairman's letter Congenital cytomegalovirus overview Minutes from meeting on 10/26/2021 Published articles provided to members United Kingdom Newborn Screening Committee Evidence Summary Condition Readiness Criteria Form completed by work group members Condition Readiness Matrix Letters of support and public comments Minutes from meeting on 1/11/2022 Submission for the State Register