**State Advisory Council on Hereditary and Congenital Disorders**

**Minutes October 9, 2018**

**Members Present** **MDH Staff**

John McGing, Chair Jed Miller

Hilary Vernon (phone)

Erin Strovel **Ex-Officio Present**

David Myles (phone) Fizza Majid

Anne Eder Johnna Watson (scribe)

Michelle Smith (phone) Robert Myers

Sarah Viall

Ben Smith (phone)

**Guests**

**Members Absent** Paul Vetter, (phone)

Delegate Karen Young Mimi Blitzer (phone)

Senator Ronald Young Richard Jones

Carol Greene

Ann Moser

**Called to Order** – 5:10 pm

**I. Welcome and Introductions**

Sarah Viall is welcomed as newest member of the Council. Ann Moser and Richard Jones are present to discuss the status of X-ALD screening in Maryland.

**II. Approval of Minutes**

Minutes from meeting on June 12, 2018 were approved with the following changes:

* DHMH changed to MDH
* Under the heading Meeting Schedule, “legislation” and “Executive order” to be changed to “statute”.

**III. Old Business**

Status of addition of new disorders

* Dr. Myers reports that the current plan is to be on-line for the 3 lysosomal disorders (LSDs) and spinal muscular atrophy (SMA) either by the 1st of January or the 1st of February of 2019. There have been significant issues delaying implementation secondary to staff turnover, but after a year long process, two new contractual staff have been hired. The LSDs using the Seeker system should be on-line by January 1st and SMA, which will be integrated into the molecular program currently performing SCID screening, should be on-line by February 1st.
* For X-ALD there has been a preliminary cost analysis, and the lab thinks it can be done with about $8 a test. There is a surplus currently since LSD and SMA but the screening have not been implemented yet. After the first quarter of the year, the lab will have a better idea as to whether or not a fee increase will be needed to implement X-ALD and to keep it sustainable into the future.
* John McGing asked if a fee increase requires a change in regulation or legislation. Dr. Myers indicates that a fee increase does require a regulation change and support from MDH. An emergency request for regulation change took about 3-4 months for the last increase. The lab needs to justify the reason for the increase, if needed. The lab also needs to be cautious in moving forward with screening and incurring a deficit in the budget which would be difficult to cover. Dr. Majid has done some initial cost analysis with PerkinElmer Genetics for reagent rental that does not require a capital investment. The reagent rental will still need to go through a procurement process.
* Dr. Carol Greene asked why the lab does not just go ahead and ask for the fee increase since $8 a baby would be difficult to cover with the current fee. Dr. Myers states there is a surplus in the budget currently, due to the delay in implementing the 4 new disorders and due to military contract providing additional income. Therefore, the lab has to see how the books balance out once LSDs and SMA screening is started. The lab cannot ask for a fee increase and create an even larger surplus. The lab is starting screening for LSDs and SMA without a fee increase, but it is unknown if they can start X-ALD without a fee increase at this time.
* Dr. Richard Jones asked what percentage of the $8 estimate is based on the cost of the kit. Dr. Majid states there is no kit at this point. The plan is to obtain the reagents from PerkinElmer and have an in-house procedure. Dr. Myers adds that staffing needs are not completely determined yet for X-ALD. The lab may be able to move people around since X-ALD will be mass spec or they may need to hire personnel. The LSDs, since it is a different platform, requires 2 dedicated staff members. SMA will be performed by staff currently performing SCID screening so no new staff is needed for SMA.
* Johnna Watson asked what follow-up plans have been determined by the genetic centers. Dr. Majid states they will have a committee of all of the genetic centers involved to set up a protocol to respond to the new disorders on the screen. Sarah Viall states Children’s already has protocols in place because DC has started screening for MPS-I and Pompe. She will share these protocols. Dr. Majid will send out a Doodle poll to determine date and time for meeting.
* John McGing provided a summary at the end of the discussion. Recapping that screening for LSDs and SMA is planned to be on line in January/February 2019 and the 5th disorder, X-ALD, needs more budgetary analysis prior to implementation.
* Dr. Ann Moser offered her assistance in setting up screening for X-ALD and KKI will be available for any follow-up testing that is needed. She also indicated Dr. Ali Fatemi at Hopkins is also running a clinic seeing patients with X-ALD so he is available for consult as well.
* Dr. Greene asked if diagnostic testing can be sent to KKI regardless of insurance coverage. Dr. Jones states the testing can be done through the grant KKI has with the State of Maryland to cover costs of the testing if needed.
* Dr. Greene states that the Society for Inherited Metabolic Disorders meeting will be happening during the next scheduled meeting time of April 9th. Sarah Viall states the National Newborn Screening Symposium is April 7th-10th, as well. John McGing indicates we will reschedule the next meeting and we will discuss this issue again at the end of the meeting.

Letter regarding reimbursement for genetic counselors

* Johnna Watson reports the letter regarding reimbursement for genetic counselors was finalized and mailed to Dennis Schrader, CFO for Medicaid, on August 9, 2018. There has been no response at this time.
* Discussion ensued regarding the change of the intent of the letter which initially was to address the lack of coverage for genetic testing through Maryland Medicaid (MA). Dr. Greene states microarrays are not being covered by Maryland Medicaid (MA). Sarah Viall states they were having this issue as well and they talked to MA. There appears to have been a mistake in Maryland MA and the wrong codes were being used. Some codes are being covered, and she will share with others.
* John McGing encouraged the genetic centers to share the codes with each other to determine if the problem has been resolved.

**IV: Member Updates**

* Laboratory Administration

No additional updates provided

* MCHB

Dr. Jed Miller reported that Dr. Howard Haft, former Deputy Secretary for Public Health Services, is now with a new program called Maryland Primary Care. Fran Phillips has been named as the Deputy Secretary for Public Health Services. Ms. Phillips was in this position from 2008-2013, and she has been re-appointed under Secretary Neall.

* Johnna Watson reports that the Federal Advisory Committee is meeting in 2 weeks and they are now looking at a new disorder, cerebrotendinous xanthomatosis (CTX) to see if this disorder should be moved forward into review process. Dr. Moser states this is a lipid disorder and babies with this disorder can have malabsorption and liver dysfunction. If left untreated, dementia can develop in the teens. Testing is through bile alcohol measurement through mass spectrometry. Dr. Moser is working on setting up a combined screen for X-ALD and CTX.
* Sarah Viall reports that Virginia is going live with screening for Pompe and MPS-I on January 1, 2019. They have voted to include SMA but it may be another year. They are still working on X-ALD.
* Dr. Miller reports that SMA was added to the RUSP in July, 2019.
* Michelle Smith states she has been on the newborn screening website, and some of the links are not working. Dr. Majid reports the lab website is currently being updated.

**V. Future Topics for Discussion**

* John McGing asked if members had any topics they would like addressed at future meetings. No response noted.
* Dr. Greene requested that the issue of reimbursement be discussed at the next meeting. She suggested inviting some of the genetic counselors who work in the clinics to come in to discuss the issue. Dr. Hilary Vernon states that she was told there were some codes that were not working but different codes were working. John McGing states if it is just an issue of codes needing to be changed, then it is not an issue for this Council. He reiterated the need for discussion among the genetic centers to share the appropriate codes and if the issue is not resolved, then the Council could hear a presentation on the issue to get a better idea of what the problem is and if there is anything that can be done.
* Sarah Viall asked if there could be a summary of the implementation of LSDs and SMA screening at the next meeting since it will be a couple months in process.

**VI. Next Meeting Date:**

* The members of the Council selected April 23rd as the next meeting date instead of April 9th as originally planned to avoid conflicts with the two national meetings. Meeting will be held April 23, 2019 at 5:00-7:00 pm at 201 W. Preston Street. Reminder and call-in information will be sent prior to this meeting.

**VII. Adjournment**

Meeting adjourned at 5:48 PM.