MARYLAND
Department of Health
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Laboratories Administration
Robert A. Myers, Ph.D., Director
1770 Ashland Avenue
Baltimore, Maryland 21205

Minutes of Meeting – March 27, 2018

The Laboratory Advisory Committee (LAC) meeting took place at the Maryland Public Health Laboratory, Conference Room 128E, located at 1770 Ashland Avenue Baltimore, Maryland 21205. Dr. John G. Newby called the meeting to order at 11:00AM.

Members Attending: John G. Newby, Chair, American College of Pathology (via video conference)
Barbara S. Caldwell, American Society of Clinical Pathologist
Cherokee Layson-Wolfe, Pharmacist
Piyush K. Patel, American College of Physicians
Malcolm R. Rubinstein, Consumer Member
Paul Celli, Public Health Administrator, OHCQ (via teleconference)
Gail McGucken, Laboratory Surveyor Scientist II, OHCQ

Other Attendees: Dr. Robert Myers, Director, Laboratories Administration
Rodney Hargraves, Deputy Director, Administrative and Support Services
Renee Scurry, Administration, Regulatory and Administrative Services
Hope Miller, Paralegal II, Regulatory and Administrative Services

Members Absent: Lindsey Howard, Jr., Industry
Robert Yim, American Academy of Pediatricians

I. NEW BUSINESS

A. Welcome and Introduction of New Members (11:00AM)

Dr. Newby welcomed everyone to the first LAC meeting of 2018. The new appointees were also recognized and welcomed. They are:

- Barbara S. Caldwell, American Society of Clinical Pathologist;
- Piyush K. Patel, American College of Physicians; and
- Malcolm R. Rubinstein, Consumer Member

B. Overview of the Laboratory Advisory Committee PowerPoint Presentation (11:10AM)

Due to several recently appointed new members, Dr. Myers provided a PowerPoint presentation on an overview of the Laboratory Advisory Committee. The PowerPoint was intended to provide new appointees with information concerning the purpose of the Committee, duties, responsibilities and expectations.

Topics included (1) creation of the Laboratory Advisory Committee, (2) tests approved for excepted status, (3) composition of the Laboratory Advisory Committee, (4) expectations of Committee appointees, (5) role of the Laboratories Administration, (6) frequency of laboratory advisory committee meeting and (7) communication between laboratory advisory committee appointees.

C. Vice Chair Appointment (11:18AM)

The Laboratory Advisory Committee is in need of a Vice Chairman. The Vice Chair will serve in the absence of Chair; and ideally, the Vice Chair should be a clinician or in a clinical specialty.

To serve in this capacity, Dr. Newby nominated Dr. Piyush Patel as Vice Chair and Ms.Gail McGucken second the motion. Dr. Patel thereafter agreed to serve in this capacity. There were no objections and Dr. Patel's nomination received unanimous approval by the Committee.

D. OHCQ Presentation – Licensing and Regulation of Clinical Laboratories (11:21AM)

Paul Celli, Public Health Administrator for Clinical and Forensic Laboratories, Office of Health Care Quality, provided an update on licensing and regulation of clinical laboratories. This quarter, the Office of Health Care Quality noted that there are four clinical laboratories that are currently facing CLIA inspection deficiencies. Of these four, two may be referred to CMS for sanctions; a drug testing laboratory lacked a laboratory Director for three months; and one hematologist has been highly uncooperative in responding to OHCQ findings.

The licensing staff for the Office of Health Care Quality is also working on renewals for Tissue Banks and Independent Reference Laboratories that will expire in June 2018. Currently, physician office laboratories (POL's) total 2,051, of which 881 are performing excepted tests, 1,050 are performing excepted and non-excepted tests and 120 are performing only non-excepted tests.

Finally, as an update on the Stem Cell company in Florida seeking Tissue Bank licensure, the State of Florida has declared that it does not recognize U.S. Stem Cell Clinic of Sunrise as a Tissue Bank since they are currently working with a FDA IND (Investigational New Drug, i.e. unapproved stem cell treatment). The IND stem cell treatment is considered to be an unproven and unsafe product that will potentially place patients at significant risk. Regardless, the U.S. Stem Cell Clinic of Sunrise is seeking AABB (American Association of Blood Banks) Accreditation so they can gain licensure for a pediatric cardiac stem cell study at Johns Hopkins Hospital.

In Maryland, this company is considered to be a tissue bank under COMAR 10.50.01, but would be subject to inspection for licensure.

E. Update House Bill 681 (11:25AM)

Renee Scurry provided an update on House Bill 681- HB 681- Medical Laboratories – Advertising or Solicitation of Business – Repeal of Prohibition. House Bill 681 (which was also introduced during previous legislative sessions), repeals a prohibition on medical laboratories from directly or indirectly advertising to and/or soliciting business from anyone other than a physician, hospital, medical laboratory, clinic, clinical installation, or medical facility.

Ms. Scurry explained that this legislation is driven by 23andMe, a DNA genetic testing and analysis service. During the past several years, 23andMe has been trying to obtain authorization to sell its products in the State of Maryland. However, Maryland is one of two states that does not allow direct-to-consumer testing (New York is the other). As stated by Dr. Rubenstein, the other 48 states Although the Department has not yet crafted its response for this bill, a letter has been drafted on behalf of the Laboratory Advisory Committee concerning the potential impact this bill may have if enacted in the State of Maryland.

As drafted, this bill may cause unnecessary physician office visits or may lead physicians to incorrect conclusions due to inaccurate, incomplete or misunderstood information. In addition, many health care practitioners may not be familiar with the information provided by un-validated genetic testing and will be required to expend a considerable amount of time researching genetic testing results to sufficiently advise patients on potential genetic conditions and available treatment. This can potentially cause an increase in patient healthcare spending and/or increased insurance premiums if costly pre-existing conditions are found.

There is also the issue of genetic testing companies selling consumer genetic information to outside companies for marketing. In most instances, the consumer is unaware of this practice which causes privacy concerns. Finally, enacting the current bill would allow out of state laboratories, not licensed by Maryland, to perform unregulated testing; and the potential for harm is significant.

Dr. Patel agreed with the concerns expressed by the Committee and added that in many cases, health insurance companies are not willing to cover the cost of genetic testing whereby creating significant out-of-pocket expenses for the patient. Moreover, as per Ms. Caldwell, these tests can be very expensive. Finally, although Maryland and New York do not permit direct-to-consumer genetic testing (without physician involvement), a loop hole for testing may exist since LabCorp, which is licensed and operates in both states for clinical testing conducts genomic testing for 23andMe.

F. Additional Items (11:38AM)

Abbott Piccolo Chemistry Analyzer

Although the Abbott Piccolo Chemistry Analyzer is not on the agenda (since a formal request has not been submitted to add this instrument to the list of excepted tests under COMAR 10.10.03.02), Dr. Newby felt that this analyzer was worthy of discussion.

On February 8, 2018, Dr. Myers received an inquiry from the Maryland Department of Health, Office of Governmental Affairs on behalf of Delegate Sid A. Saab. Delegate Saab inquired why the Abbott Piccolo Chemistry Analyzer required weekly inspections when federal regulations required monthly inspections for this type of instrument. The Abbott Piccolo Chemistry Analyzer is a CLIA waived diagnostic analyzer that offers a full complement of blood chemistry tests.

In response to Delegate Saab's inquiry, the Office of Health Care Quality replied that the Abbott Piccolo Chemistry Analyzer is CLIA waived for a basic chemistry electrolyte panel (i.e. sodium, potassium, glucose and lipids). It is considered to be of moderate CLIA complexity and is non-waived for other analytes. In addition, the Abbott Piccolo Chemistry Analyzer it is not on the Maryland "excepted list of tests" and therefore, requires a full Maryland lab permit.

The analyzer also requires single use quality control testing using at least two levels of control materials run once per week (as per COMAR 10.10.06.06). It was believed that the Laboratory Advisory Committee implemented this more stringent quality control protocol because of (1) the clinical importance of these qualitative tests results, (2) the need to ensure accuracy and precision of the analytic phase of the testing process, and (3) the need to ensure proper testing personnel practices during the testing process.

However, the Laboratory Advisory Committee does not have any records or institutional memory of ever evaluating the Piccolo Chemistry Analyzer for inclusion as a CLIA waived test (for certain analytes on the list of "Excepted Tests" under 10.10.03.02).

Typically, health care providers and/or the test kit/test system manufacturer will generally submit a request to the Laboratory Advisory Committee to consider placing a test on the list of excepted tests. Upon consideration and upon performance of a risk-benefit analysis by the Committee, a recommendation is submitted to the Secretary on whether "excepted status" should be granted for the test, with or without conditions. Consequently, Delegate Saab's inquiry seems to place the Laboratory Advisory Committee on notice that a request will probably be forthcoming to consider the CLIA waived Piccolo Chemistry Analyzer tests for excepted status.

As a point of reference, the Laboratories Administration has a Piccolo Chemistry Analyzer which is operated under its CLIA license, along with proficiency testing and other quality assurance measures, to ensure that quality results are produced. Therefore, the Laboratories Administration does not need a State waiver to perform testing on this instrument.

Ms. Gail McGucken noted that an Urgent Care Center on the Eastern Shore is planning to use the Sysmex Automated Hematology Analyzer to perform testing. This analyzer has been waived by the FDA, but is not on the excepted test list in the State of Maryland. It is a complete CBC blood count analyzer which can detect a range of disorders including anemia, infections and leukemia.

However, CBC testing depends heavily on proficiency testing, and waiving this test without a proficiency testing requirement is not safe. Dr. Newby thereafter suggested that literature should be requested from the manufacturer for review by the Committee in the event a formal request is made to the Secretary to consider this analyzer for excepted status.

Cherokee Layson-Wolfe

Ms. Cherokee Layson-Wolfe, Pharmacist, has decided not to seek reappointment to the Laboratory Advisory Committee. However, Ms. Layson-Wolfe has agreed to remain on the Committee until another Pharmacist is appointed. She also agreed to provide the names of a few qualified Pharmacists for consideration as her replacement. Dr. Newby thanked Ms. Layson-Wolfe for her years of dedicated service and wished her the all the best in her future endeavors.

II. AJOURNMENT

The meeting was adjourned at 12:00PM.

Respectfully submitted,

Renee Scurry and Hope Miller
Office of Regulatory and Administrative Services
MDH Laboratories Administration