Division of Public and Behavioral Health
Medical Laboratories Advisory Committee
MINUTES
DATE: March 25, 2022
TIME: 12 p.m.

Meeting Locations:

- This is a virtual meeting and there is no physical location to attend.
- Click here to join the meeting
- 775-321-6111
    - Conference ID 566 692 622#

Agenda items may be taken out of order, combined for consideration, and or removed from the agenda at the chairperson's discretion.

1.) Call to Order and Roll call – **Chair**

Members:

Christie L. Elliott, M.D.
David P. Marmaduke, M.D.
Alexander Stojanoff, Ph.D.
Victor M. Muro, M.D.
Iain L. O. Buxton, Ph.D.
Jill Brown, MT
Ihsan Azzam, M.D., Ph.D. Chief Medical Officer State of Nevada, ExOfficio
Medical Technologist-Vacant Position
Pierron Tackes, Deputy Attorney General
Leticia Metherell, Health Program Manager, RN

Staff:

Bradley Waples, Acting Manager Medical Laboratory Services
Emma Duarte, Acting Supervisor Medical Laboratory Services
Nikki Feister, Administrative Assistant III

Quorum was met- Christie L. Elliott, David P. Marmaduke, Alexander Stojanoff, Victor M. Muro, Iain L. O. Buxton, Jill Brown, Ihsan Azzam, and Pierron Tackes in attendance.

Brad Waples is acting chairman at this time, we will be electing a new chairman at our next meeting: Friday, October 7, 2022.

2.) Public Comment

- Action may not be taken on any matter brought up under this agenda item until scheduled on an agenda for a later meeting. Public testimony under this agenda item may

be presented in person, online, by phone or written comment. Due to time considerations, each individual offering public comment will be limited to not more than three minutes.

Nathan Orme asks for people on video to raise their hands and we would answer questions from there first. No raised hands on Teams, moving to call ins.

Jason Miller, respiratory department, UMC in Las Vegas, called in regarding section 6 and 7 regarding to Armed Services which was generated from UMC. Under NRS 630 the training of army personnel would be trained and educated for their Blood Gas licensing, he is in support of this and is asking for full approval on section 6 and 7.

3.) Discussion and possible action to review, update and approve the MLAC committee bylaws - Action Item.

Two recommendations were made by Brad Waples. The first was to change the name from Bureau of Licensure and Certification to be updated to the Division of Public and Behavioral Health, location is at: 727 Fairview Dr., Suite E, Carson City, NV 89701. The second recommendation is the frequency of the meetings to be changed from two times a year to at least one time a year to meet. Dr. Muro made a motion to accept the recommendations, Dr. Stojanoff second, motion passed unanimously.

4.) Discussion and possible action to make recommendations to the Division of Public and Behavioral Health regarding the proposed revisions to the Nevada Administrative Code (NAC) Chapter 652, in LCB File No. R126-21 relating to subjects listed below, including a review of public comments received and the Small Business Impact Questionnaire.

- Sections 1-3: This regulation change is to create a pathway for a "Licensed Laboratory for the Specimen Collections only."

Brad Waples mentioned the approved changed by LCB regarding a pathway for licensed laboratories that collect specimens, would need to include testing by a laboratory director to hold a PhD or a pathologist. This limited the Phlebotomists who wanted to create their own businesses during the pandemic were collecting specimens from providers, then taking the collection to a CLIA Certified Laboratory for analysis. This was mainly in the rural areas where people could not leave their homes due to the pandemic. The laboratory director who is collecting specimens identified themself in either, 652.155 category, which the MD, DO, PhD, PRN, a PA, or a General Supervisor of a laboratory to be a laboratory director and the cost is less as well which will help fill the void for our state.

No recommendations for section 1-3

- Section 4: This is the qualifications for a General Supervisor with a Specialty (which currently does not exist) and describes their scope of practice.

Brad mentioned a general supervisor with a specialty doesn't currently exists, this section goes over the qualifications and scope of practice for a general supervisor with a specialty. Discussion on what "specialty" is referring to from Dr. Stojanoff using the example of a general supervisor of toxicology, they would only be a general supervisor of that area of expertise, toxicology, not over a full laboratory, unless they hold a general supervisor license in all areas. The reason this has been brought up is some specialty technologists would like to have a general supervisor license, this creates a pathway for them to work in this capacity. Currently, a specialty technologist does not have this ability to work as a general supervisor.

Dr. Muro asks Brad, that would apply for the blood draws only and not the analytic associated with specimen collected? This is for 1-3 section for clarification, on laboratories that do the collection only, and not perform any laboratory testing. The collected specimens would go to a CLIA-certified Laboratory for analysis. The licensed laboratory for collections only, will not require a general supervisor. Monitoring the physician's licensure which is a general license will be done through inspections. The documentation during the inspection will show what areas they've been working on and what specialty, so they would be sited a deficiency if they are working outside of their license.

Emma also mentioned some medical technologists only have hematology and would be required to have general supervisor license, especially for hospital laboratories which are a 24/7 operating hours. Medical technologists with the background of hematology that have a general supervisor license would be able to help the other general supervisors and oversee in a licensed laboratory in hematology.

A question from Mollie Kircher (from the public) regarding if the specialty technologist gets their general supervisor license will they still meet the qualifications. Brad Waples answers, yes, they would still need to meet the same qualifications as a general supervisor, he referred Mollie to look at the regulations, NAC 652.478 and that the technologist would have to meet the criteria with 3 years of experience, working full time at least 30 hours a week in a licensed laboratory, college or university specialty, in which he/she is certified with at least 2 years spent working as a technologist and under the supervision of a director with doctoral degree.

Pierron helped the public participants to be aware of public workshops and hearings on these regulations, which they can attend these meetings. The discussion today is for members of the public body.

A question from Dr. Stojanoff: Is it okay to have many specialties licensures? Brad answered, yes, they have met all the requirements for each of these specialty areas.

Dr. Marmaduke suggested to change the name from general supervisor with a specialty to section supervisor, since a general supervisor covers the whole laboratory in all areas. Brad clarified the license would read general supervisor of whatever that specialty is like microbiology or a personnel technologist under that specialized area.

No recommendations for section 4, Dr. Stojanoff supports this.

- Section 5: This describes what is required for person who wishes to receive equivalent credit toward a personnel license pursuant to Assembly Bill 330.

The applicant would show proof of transcripts and course training completion to obtain this license.

No recommendations for section 5

- Sections 6-7: Also refers to updated terms and includes a regulation that allows members of the Armed Services to receive training in a Nevada hospital without having to obtain a State of Nevada Medical Laboratory Personnel license.

This section allows members of the Armed Services to receive training in Nevada hospitals without having a Nevada Medical Laboratory personnel license, this is the same section Mr. Miller was referring to earlier.

No recommendations for section 6-7

- Section 8: Allows for Division of Public and Behavioral Health inspectors to inspect any premises to ensure compliance with NAC Ch. 652 regulations and statutes including request for documents.

This section identifies places that were doing laboratory testing but were not licensed by the state of Nevada. We would inspect the building, premises, and secure any information as to keep them compliant with Chapter 652 or NRS and NAC.

For clarification, these are not licensed laboratories that are performing these clinical lab tests, per Dr. Stojanoff.

A discussion from Dr. Muro: If they are not licensed, how do we have regulatory oversight over them?

Brad informed the committee that a complaint had been filed on an unlicensed laboratory. During the investigation of the unlicensed laboratory, we requested any documents to fulfill the complaint investigation. If an unlicensed laboratory is doing testing on the public, we ask them to do a voluntary cease and desist, we collect information that supports evidence of not being licensed and what tests they are performing. There was a contracted company, we checked to see if they were licensed, they were not. They had been collecting specimens and then sent them to a CLIA-Certified Laboratory outside of the state. The contracted company would have to have a laboratory license to do the collection, when asked for documentation, they refused to give documentation or to talk to us and this is what the regulation is for and to support the complaint investigation. If they do not cease and desist, then we would have the attorney general's office for enforcement.

No recommendations for section 8, Dr. Stojanoff supports this

- Section 9: Updates the qualification requirements for a Ph.D. who wants to be a Licensed Laboratory Director.

Brad mentioned that a PhD in chemical hygiene requested to be a laboratory director, this person holds a doctoral degree in chemical physical or biological science, however their experience is in a nonclinical format. This person would need to have clinical experience and would be performing laboratory tests on human, and they would need to have all the nuances of what's required for state and federal regulations.

Dr. Muro asked: If they have a PhD can they be a licensed laboratory director?

Brad responded that someone with a PhD, a toxicologist, meeting all the requirements, they can be a licensed laboratory director over the area in which they are not a PhD in. Pathology, specimens, microbiology cultures, chemistry and analytics would fall under this area of oversight.

Dr. Stojanoff asked about Anatomical pathology would not fall under this license, since the MD would have to have a specialty in anatomical pathology or medical cytology.

Dr. Muro mentioned pathology is a subset of overall supervision and is very broad to exclude analytics and specimens for pathological reporting.

Dr. Stojanoff mentions laboratory directors that have Anatomical pathology qualifications can also direct clinical laboratories, not being in a specialized clinical laboratory.

Brad referred to NAC 652.380, for a physician who is a pathologist, must be certified in anatomic and clinical pathology or in clinical pathology. They wouldn't be if they were just an anatomic pathologist they wouldn't qualify as a licensed laboratory director.

No recommendations for section 9

- Section 10: Updates the qualification requirements for a Ph.D. who wants to be a Registered Laboratory Director.

Brad mentioned this is the same as section 9 but dealing with registered laboratory director instead of a licensed laboratory director.

No recommendations for section 10

- Section 11: States the qualification for a laboratory director for a Licensed Laboratory for Collections Only and includes dentists as qualified laboratory directors of Exempt laboratories.

Dr. Stojanoff mentioned that dentists should have laboratory training whether it be a registered laboratory.

Brad mentioned exempt laboratories can only perform waived laboratory tests, so they would be limited to their scope of practice and can offer to a waive laboratory tests. Dentists do have some chemistry background, for the waived laboratory testing they would be able to have COVID testing before the patient comes in or diabetes with glucose testing. They would have to be inspected before any kind of testing; the State of Nevada requires that all laboratories are inspected before any testing and meets all the requirements.

Dr. Stojanoff is concerned on the training of the dentist and if they are properly trained enough in laboratory training, and concern on legislation.

Brad agrees with Dr. Stojanoff, however the federal CLIA requires waived laboratory testing have two things. One, you follow the manufacturer's direction and two, the test must be done in a waived laboratory. The laboratories that have a laboratory director must have a person with medical background and would oversee the laboratory from a federal perspective. It could be anybody. It could be a janitor that was the laboratory director in the federal system and medical background would be required for a laboratory director to oversee the operation of any laboratory tests. This person would meet the needs of our community as well as having a medical background.

Dr. Buxton asks about the range of tests on exempt tests.

Brad answered that by the range of tests have become more as the years progressed because of technology. They it could be finger stick glucose is it could be hemoglobin. A one CS it could be cholesterol screenings. There's quite a few waived laboratory tests and the FDA is the one that categorizes the laboratory tests into waived or non-weight testing and so it's up to the FDA to decide. A lot of waived laboratory tests have been able to do COVID tests, not to include hematology. There's some like strep tests, urine dipsticks but nothing in immunohematology or pathology.

Dr. Buxton is concerned with the dentists that have expanded their traditional dentistry to lipid testing and could be a risk to their patients with this information.

Brad explained this gives the dentist an opportunity to be licensed by the regulations and doing it correctly instead of being out of compliance.

Dr. Muro is concerned that dentists would are performing tests and are not covered under their license that they could fall into a “pitfall” which means we would go after them directly, instead of creating an environment which leads to a broader level of activity.

Dr. Azzam mentioned they saw many times during COVID 19, when providers refused to see a patient without a covid test, these patients were left unseen. It’s better for the provider to do the test and see the patient instead of leaving them without care, this has happened in other specialties as well as dentistry.

Recommendations for section 11

Dr. Marmaduke did not agree with the thinking on this, and dentists should do the right thing and therefore not change the code because of their misbehavior.

Dr. Stojanoff agrees and second.

Dr. Elliott had a question on changing the code.

Dr. Muro said that to change the legal standards is a bit backwards. If a dentist wishes to do these tests, then the structure would need to be in place. The way it's worded, there's a lack of structure, which would create noncompliance. Structure first then when they have fulfilled that requirement then they can be approved to do testing.

Dr. Buxton mentions access to care which is first and then second issue is the range of testing to which they are restricted and is not in support of this recommendation.

Nathan checked with Pierron, and we will come back to Section 11 for a vote separately.

- Section 12: This regulation update allows for a Licensed Laboratory of a hospital that has one standalone Emergency Department at another location to be able to have a General Supervisor of the main hospital laboratory to be able to be the General Supervisor of the standalone ED as long as all of the specified stated items are met.

Brad informed us that the licensed laboratories of a hospital may have standalone emergency department at another location. They would be able to have a general supervisor to the main hospital and to be the standalone ED as long as all specified dated items are met. Many popups in Nevada for example, Mountain View Hospital has a couple locations and general supervisors are hard to find. To be in compliance with state regulations, they are finding it hard to find people that are qualified to be general supervisors at these multiple locations. The laboratory general supervisor of the main laboratory, using Mountain View Hospital hypothetically, one of the requirements is to be on site at least once a month at the stand-alone emergency department to make sure the tests are being performed in accordance with the restrictions and manufacturer's test to fulfill federal and state laws and regulations. The standalone ER would only do care testing and waive laboratory testing.

Dr. Stojanoff asked if there was a patient who was having a heart attack and after many blood samples and there wasn't a general supervisor on site, there was someone with limited experience running the tests, this would be a problem?

Brad reiterated that the standalone would only be allowed to perform ER waived laboratory tests or point of care tests. Point of care test means anything that can be done at a bedside, example: i-Stat, Kim 6, PT, PTT, or many other types of i-Stat test, also waived tests can be done. Test that cannot be done are large instruments like large chemistry analyzers or things like that which are not under this regulation. Due to the shortage of general supervisors in a hospital, the hospitals do want to be compliant it's hard to find qualified people, so this is to bridge the gap and keep them complaint.

Dr. Elliott asked for clarification on the main laboratory doing tests which are to complex and has the general supervisor and outside of the waive or point of care test. If the stand-alone ER gets a complex test, they will send it to the main laboratory?

Brad mentioned, the standalone are limited to either point of care which are bedside instruments being used or the is that for any waived testing like a rapid strep, or urine dipstick, or finger stick glucose. The standalone is 15-20 minutes away from the main hospital.

No recommendations for section 12

- Section 13: This regulation updates qualifications for General Supervisors.

This was brought up because a medical technician who have been working for 3 years wanted to use their time and experience towards their 3 years of medical technician training experience to qualify for a general supervisor. This would not be allowed due to not operating or doing laboratory testing at a technician level is limited and that's why we want to put section 13 into regulation. This added verbiage to say that the person needs to have at least 2 years working at the technical technologist level to identify exactly what they need to have.

No recommendations for section 13

- Section 14: This regulation updates the Technologist level of personnel license.

We want to specify that their training and experience must be in a clinical laboratory, water analysis at a technologist level is a high complexity testing which is not clinical testing, and we would not accept that. This needs to be specific in the regulations and clarify anything that would create ambiguity to what the requirements are.

No recommendations for section 14

- Section 15: This regulation update allows for Certified Nurse Assistants and nursing students to be able to perform glucose as a point-of-care analyst.

This is to help with shortage by the nurses who are involved in other areas, the nurse assistants and students that are enrolled in an accredited school or professional nursing or graduated to be able to do finger stick glucose only.

No recommendations for section 15

- Section 16: Updates the qualification requirement for Specialty Technologists to have "clinical" experience at the level of the technologist to be qualified for the personnel license.

This is to clarify the experience and clinical nature of the level of a technologist for testing.

No recommendations for section 16

- Section 17: Updates requirements for Laboratory Assistants to receive a personnel license that specifies acceptable areas to receive training.

No recommendations for section 17

- Section 18: States the fees associated with a Licensed Laboratory for Collection Only.

The fee for a Licensed Laboratory for Collection only is $500.00 for initial, $300.00 for annual and $500.00 for reinstate for a license.

No recommendations for section 18

- Section 19: Refers to a change in the numbering of a subsection that is being referenced.

These are the proposed regulations.

Dr. Stojanoff requested a copy of the recommendations for the purposed regulations, Nathan has added the link to the chat section of teams.

Dr. Muro requested Nathan email a copy to them as well.

No recommendations for section 19

Dr. Muro made a motion to approve section 1-10, 12-19 and a separate vote for section 11. Dr. Buxton second, all in favor with 1 oppose, motion passes.

- Section 11 voting (not to support the dentists) these are recommendations from the committee to make these changes and are requesting to the board of health.

Dr. Buxton recommends the dentists not be included. Dr. Marmaduke second,

Three in favor *(these votes are for **not** in support of dentists being lab directors)*, with four opposed *(these **are** in support of dentists being lab directors of an Exempt laboratories)*, motion passes in support of allowing dentists to be laboratory directors of an Exempt laboratory.

Pierron Tackes, Deputy Attorney General, said that the committee was created in statue to advise the Division of Public and Behavioral Health relating to medical laboratories and the qualifications of laboratory directors and personnel. These regulations were brought to the committee to get recommendations, and any other comments that you might have on these draft regulations. This committee does not have the authority to pass any laws. These regulations will go through the standard process, which are established in the statute. They'll be taken to a public workshop, or the public will have an opportunity to make public comment as well as a public hearing before the Board of Health where they'll be able to make public comment and it's the Board of Health, which will pass these regulations at that point. These regulations requests then go to the Legislative Commission and there they will give the final stamp of approval before these go into effect. The purpose of today's meeting is to get the committee members opinions and recommendations on this draft.

5.) Approval of meeting minutes from 10/12/2016 - Dr. Muro makes a motion, Jill Brown second Action Item

6.) Determine date of next meeting (dates of future meetings subject to change):

Friday, October 7, 2022, at the same time 12:00 pm, we will need to appoint a chairman, which we will do at the October meeting, and we will review the recommendations of the regulations. The chairman's duty is to perform running the meeting, taking part of creating the agenda, point of contact for the medical laboratory advisory committee, letter drafting, recommendations, operational things, and information about the personnel side. This will be an agenda item for the next meeting, think about who or if you would like to be that new chairperson.

Dr. Elliott requested to have the LCB file to review prior to the meeting to be ready for future meetings instead of just bullet points to read it in-depth. She would like to receive the attachment prior to the meeting for next time. Nathan explained LCB won't be every meeting, he put it in the chat section of Teams to access and we will send it to her.

Dr. Stojanoff has some agenda items he will like added to the next agenda, he can contact Nathan Orme or Nikki Feister

7.) PUBLIC COMMENT

- Action may not be taken on any matter brought up under this agenda item until scheduled on an agenda for a later meeting. Public testimony under this agenda item may be presented in person, online, by phone or written comment. Due to time considerations, each individual offering public comment will be limited to not more than three minutes.

John Phoenix (public) that the committee would benefit from some diversification and inclusion from non-physician providers and community members. This will help bring in enhancement of the responsibilities of this community, reporting, and awareness to those entities that are out of compliance.

Suzanne Hunter (public) patient care during the COVID experience, how some people are taking advantage and they are not qualified, these people are starting laboratories that are very dangerous to patient care. These people come in from other states and setting up laboratories under other people's names. Some hire a pathologist for once a month to get their qualifications and certificate. She appreciates that we stay vigilant on patient care and licensing to keep the community safe.

Dr. Muro was asking about committee members for John Phoenix. Brad mentioned per bylaws and legislature we have criteria to follow 2 pathologists, a biochemist, bio analyst and 2 medical technologists are members of the committee.

Brad thanked the committee members for attending and it was a great meeting.

8.) Adjournment at 1:45 p.m.

AGENDA POSTED AT THE FOLLOWING LOCATIONS:
On the Internet at the Division of Public and Behavioral Health website
and at https://notice.nv.gov/

AGENDA EMAILED FOR POSTING AT THE FOLLOWING LOCATIONS:
Division of Public and Behavioral Health, 4220 S. Maryland Parkway, Bldg. A, Suite 100, Las Vegas, NV
Division of Public and Behavioral Health, 4150 Technology Way, Carson City, NV
Division of Public and Behavioral Health, 727 Fairview Drive, Suite E, Carson City, NV

We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. In the event of Microsoft Teams application has technical difficulties, the meeting may be conducted by teleconference from the same location. If special arrangements are necessary, please notify Nikki Feister, Division of Public and Behavioral Health, in writing please send to, 727 Fairview Drive, Carson City, Nevada 89701 or by calling (775) 684-1033 before the meeting date. Anyone who wants to be on the advisory council mailing list can sign up on the listserv at http://dpbh.nv.gov/Reg/HealthFacilities/dta/Lists/Listservs/.

If you need supporting documents for this meeting, please notify Nikki Feister, Division of Public and Behavioral Health, Bureau of Health Care Quality and Compliance, at 775-684-1071 or by email at nfeister@health.nv.gov.