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National Provider Call Transcript

Centers for Medicare & Medicaid Services
CLIA Certificate of Provider-performed Microscopy Webcast
MLN Connects National Provider Call
Moderator: Nicole Cooney
June 28, 2017
1:30 pm ET

Contents

Operator: Hello and welcome to today's event. My name is Jen, and I'll be your web event specialist today. All lines have been placed on mute to prevent any background noise. Please note that today's event is being recorded. During the presentation, we'll have a question-and-answer session. You can ask text questions at any time. Click the green Q&A icon on the lower left-hand corner of your screen, type your question in the open area, and click Submit. We will also be taking questions via the phone lines, and instructions on how to do so will be given at the appropriate time. If you would like to view the presentation in a full-screen view, click the Full Screen button in the lower right-hand corner of your screen. Press the Escape key on your keyboard to return to your original view. For optimal viewing and participation, please disable your pop-up blockers. And finally, should you need technical assistance, as a best practice, we suggest you first refresh your browser. If that does not resolve the issue, please click on the Support option in the upper right-hand corner of your screen for online troubleshooting.

It is now my pleasure to turn today's program over to Nicole Cooney. Nicole, the floor is yours.

Announcements and Introduction

Nicole Cooney: Thanks, Jen. Hi, everyone. I'm Nicole Cooney from the Provider Communications Group here at CMS. And as today's moderator, I'd like to welcome everyone to this MLN event on CLIA Certificate of Provider-performed Microscopy Webcast. MLN events are part of the Medicare Learning Network®. During today's event, you will learn about the Clinical Laboratory Improvement Amendments, or CLIA, requirements for provider-performed microscopy testing.

Before we get started, there are a few items I'd like to quickly cover. Today's event uses webcast technology. We recommend streaming the audio live through your computer speakers. Those of you participating via webcast may download a copy of today's slide presentation by clicking the blue Files button at the bottom left side of your screen. And please note that this event is being recorded and transcribed.

I'd like to now introduce our two speakers for today's session. Our first speaker is Ms. Alana McCoy. Ms. McCoy is a medical technologist and is currently working in our CMS Region 4 Office located in Atlanta, Georgia. Our second speaker is Ms. Leah Ferrier.

Ms. Ferrier is also a medical technologist. She is located in our CMS Region 9 Office located in San Francisco, California.

At this time, I'd like to turn the presentation over to our first speaker, Ms. Alana McCoy. Alana?

Presentation

Alana McCoy: Good afternoon, everyone. Let me first start by thanking everyone for taking time out of your busy schedule to attend this webcast. I hope that everyone has had a delightful and fulfilling lunch, and if not, we will try to make this presentation as quick and transparent as possible so that you can. We have some very important information that we would like to convey to our audience regarding provider-performed microscopy testing. And with that being said, let me go ahead and get started.

Overview

Starting on slide 4, CLIA/PPM Definitions. We have defined the acronyms used in this presentation. So please feel free to refer to them as needed.

Slide 5, Learning Objectives. At the end of this presentation, the audience will have a general overview of the CLIA Program to include a brief history of the provider-performed microscopy certificate, the ability to identify applicable CLIA regulations related to provider-performed microscopy procedures, and information available to obtain free educational resources and materials to assist with meeting compliance.

Slide 6, CLIA Regulation Overview. The final CLIA regulation was published in the Federal Register on February 28th, 1992, and was made effective on September the 1st, 1992, as 42 CFR Part 493 Laboratory Requirements. These regulations established uniform quality standards for all laboratory testing to ensure accuracy, reliability, and timeliness of laboratory test results regardless of where the test was performed.

I would like place to emphasis here on all labs located anywhere. Examples would be community health fairs, physician office laboratories, nursing homes, prison clinics, and rural health facilities. Of special note, CLIA does not apply to forensic testing, patient self-monitoring, or research laboratories where the testing results are not identified individually and released to the patient or their provider. It is recommended to review the CLIA policy letters annually for new and revised policies, which are located on the

CLIA Survey and Certification website which will be provided at the end of the presentation.

Slide 7, CLIA Program Responsibilities. There are three Federal agencies responsible for CLIA—the Centers for Medicare and Medicaid Services, commonly known as CMS; the Centers for Disease Control and Prevention, commonly known as CDC; and the Food and Drug Administration, commonly known as FDA. Each agency has a unique role in assuring quality laboratory testing.

Starting with CMS. CLIA resides within CMS. So CLIA has the responsibility of clinical laboratory oversight, which encompasses issuing laboratory certificates and collecting user fees; conducting inspections and enforcing regulatory compliance; approving private accreditation organizations, such as the College of American Pathologists, C-A-P, or CAP for short, the Joint Commission, and COLA®, for performing inspections; also approving state exemptions, monitoring laboratory performance on proficiency testing, and approving proficiency testing programs; and last, publishing CLIA rules and regulations.

Next is CDC. CDC provides scientific consultation, which includes providing analysis, research, and technical assistance. CDC develops technical standards and laboratory practice guidelines, including standards and guidelines for psychology. The agency also conducts laboratory quality improvement studies, monitors proficiency testing practices, develops and distributes professional information and educational resources, and manages the Clinical Laboratory Improvement Advisory Committee, also known as CLIAC.

Last, but not least, is FDA. This agency categorizes tests based on complexity, reviews requests for waiver by application, and develops rules and guidance for CLIA complexity categorization.

Slide 8, The Definition of a Laboratory, as defined by CLIA. Any facility that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Slide 9. All clinical laboratories that perform testing on human specimens for these purposes must apply for a CLIA certificate, pay appropriate fees, and follow applicable

CLIA requirements. Note: PPM laboratories may be subject to state laboratory regulations and registration and/or licensure fees. The state's requirements are not the CLIA Federal certificate fee. Providers will need to check with your state public health department to see if there are applicable state laboratory requirements.

Slide 10, CLIA Certificate Types. There are four certificate types in which a laboratory may acquire—a Certificate of Waiver, a Certificate of – for Provider-performed Microscopy Procedures, a Certificate of Compliance, and a Certificate of Accreditation. Facilities with a PPM certificate may perform any or all of the nine microscopy procedures and waive testing. Laboratories may perform microscopy procedures under the CoC or CoA certificate. You do not need a separate PPM certificate.

Slide 11, CLIA Test Complexity. For waived testing, these are simple tests with little risk or harm if performed incorrectly. Examples are urine hCG—or urine pregnancy, urine dipstick, flu test, or a fingerstick glucose level.

Moderate complexity with subcategory of PPM procedures are commonly used hematology and chemistry analyzers. Note: moderate complexity testing does have personnel and quality requirements. We will identify the PPM procedures in another slide. Point-of-care tests can be considered moderate complexity or waived. Providers can look up the tests on FDA's website for verification. In addition, the complexity level is also designated in the package insert for the point-of-care test.

High complexity. Laboratories are certified at the highest level of testing performed. FDA determines the complexity of many tests. And noncategorized tests are considered high complexity. A few examples of high-complexity tests are Pap smears, PCR, and antibiotic sensitivity testing.

Slide 12, PPM History. Originating January of 1993, there was a new CLIA certificate type considered to be a category of moderate complexity testing. This new certificate type was physician-performed microscopy procedures, or for short, PPMP. It allowed physicians to perform certain microscopic exams in addition to waived testing during a patient's visit. The microscopic examinations were categorized as moderate complexity. The testing was limited to bright-field or phase-contrast microscopy that used specimens that were labile or in which testing delays could compromise accuracy of results. And where we note physicians, we are referring to M.D.s, D.O.s, and D.P.M.s

that are licensed to practice in the state where the laboratory is located. An additional FYI: the PPM analyzer is considered the microscope.

Slide 13, PPM History continued. PPM procedures have limited specimen handling or processing required. Also, proficiency testing or control materials may not be available to monitor the entire testing process. However, there do exist proficiency testing providers that offer some proficiency testing products for PPM laboratories. Providers can check with the manufacturer to purchase control materials or refer to the CLIA regulation regarding what to do if quality controls are not available. A laboratory may establish a quality control program as applicable for their PPM procedures. PPM laboratories are not subject to routine biennial inspections, but a CLIA certificate is required. And PPM laboratories must meet other applicable requirements, including quality standards.

Slide 14, continuing on with PPM history. In April of 1995, it was renamed provider-performed microscopy—PPM—to include other practitioners and to clarify tests that could be performed. Additional practitioners were mid-level practitioners that were licensed by the state if required. Examples are nurse midwives, nurse practitioners, or physician assistants. There are – they are all able to test under a physician's supervision or independently if authorized by the state. Also included were doctors of dental medicine or surgery. They may also qualify as PPM laboratory directors or testing personnel if licensed by the state in which the laboratory is located.

Slide 15. Now, to look closely at the PPM procedures. PPM procedures include all direct mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements; all potassium hydroxide preparations; and postcoital direct, qualitative examinations for vaginal or cervical mucus. Note: if the providers are unsure, they can check with the FDA for complexity or contact their CLIA office.

Slide 16. PPM procedures also include urine sediment examinations, pinworm examinations, fern tests, and nasal smears for granulocytes.

Slide 17, More PPM Procedures. Fecal leukocyte examinations and, last, qualitative semen analysis limited to the presence or absence of sperm and detection of motility. Please note that Gram stains and Tzanck smears are not PPM procedures. The only PPM procedures are the nine examinations listed. In addition, it is important to note that

qualitative semen analysis is limited to the presence or absence of sperm and detection of motility. Quantitative semen analysis is categorized as a high-complexity test. PPM laboratories that wish to offer a quantitative semen analysis would need to upgrade to a CoC or a CoA certificate type.

Educational Resources

Slide 18. Free educational resources are available now. The PPM good laboratory practices booklet created by the CDC was introduced in 2016 and intended to assist laboratories with understanding and meeting compliance standards for the PPM laboratories.

Tips for PPM Procedures

Slide 19. Tips in PPM procedures. The free booklet provides a general requirements checklist for PPM laboratories and many useful tips for PPM laboratory directors on preparing effective procedures and protocols for their testing personnel.

And now I will hand it over to Leah, who will provide you with additional information in regard to qualifications, requirements, quality measures, and noted resources.

CLIA Requirements

Leah Ferrier: Thank you, Alana. Now, we'll take a more in-depth look at the current CLIA requirements pertaining to human testing under the Provider-performed Microscopy Certificate. Each laboratory which tests human specimens, in order to have a CLIA certificate, must have a laboratory director identified.

Slide 20, please. This laboratory director must meet the educational and experience requirements listed in the Code of Federal Regulations 493.1355. Under a Provider-performed Microscopy Certificate, those who qualify as a laboratory director are also identified in 493.1357. These include medical doctors, doctors of osteopathy, doctors of podiatry, and dentists who hold a license in the state that they practice, as well as midlevel practitioners who qualify with a license as an independent practitioner in the state they are located and, if required, are also licensed in that state.

Slide 21. The testing personnel requirements are much the same as the laboratory director qualifications. These include physicians, M.D.s, D.O.s, and D.P.M.s as well as dentists who hold a license in the state in which they are located, and also midlevel

practitioners who are under the supervision of a physician or who are practicing independently if authorized by the state in which they are located. If the microscopy is being performed by personnel that do not meet these criteria, because the tests are considered moderate complexity, the laboratory would need to upgrade their PPM certificate to a certificate of compliance or a certificate of accreditation.

Slide 22. Testing personnel requirements – also it's very important to notify – to note that medical technologists or clinical laboratory scientists do not qualify as testing personnel under a PPM certificate. If these personnel are performing those PPM identified tests under a certificate of PPM, you will need to upgrade to a certificate of compliance or a Certificate of Accreditation.

Slide 23. Now, we'll look at the responsibilities of the laboratory director. An important point to remember is that the PPM laboratory director cannot be a director of more than five PPM- or higher certificate–types of laboratories. The five laboratory directorship restriction does not include Certificate of Waiver laboratories. So if you have three PPM laboratories or a Certificate of Compliance laboratory or two, as long as the total does not exceed five, you are okay. You may have additional Certificate of Waiver laboratories that you are a laboratory director of. But these are not included in your five limitation of directorship.

The laboratory director is responsible to ensure that testing personnel are qualified and these tests are performed during the patient's visit. The laboratory director is responsible for ensuring that the laboratory only performs the nine PPM tests referred to previously and any waived testing. And the laboratory director is also responsible to ensure that the laboratory complies with all applicable CLIA regulations.

Slide 24. Testing personnel are responsible to ensure the quality of specimen processing such as specimen collection, identification, performing the test, and reporting the test results. The test must be performed in accordance to the laboratory's identified policies and procedures.

Slide 25. Again, the test must be performed by a qualifying physician during the patient's visit on a specimen obtained from his or her own patient or a patient from a group medical practice that the physician is a member or who is an employee of that group. For dentists, the specimen must also be obtained from one of their own patients

and run during that patient's visit, or it may be a specimen obtained from a patient of a dental group that the dentist is a member of or an employee of that group still, again, during the patient's visit.

Slide 26. A midlevel practitioner may perform provider-performed procedures either under the supervision of a physician or, if they are performing as an independent practice, on their own patients. Or they are a member of a group medical practice, the mid-level may perform the PPM testing for that medical group or a clinic or a health care provider that the midlevel is a member of.

Slide 27. Some of the requirements of PPM are competency testing, the environment for the testing; the procedure manual, the quality assessment, and proficiency testing or twice annual verification of accuracy.

Slide 28. So, looking at the training and competency assessments, in order to ensure quality test results, the testing personnel as well as those who assist in the preanalytical, analytical, and postanalytical testing, must be trained and monitored during performance to verify that they are complying with testing procedures and the laboratory policies. This training and monitoring of competency must be documented. For a solo practitioner, this may require a little creativity. Using peer review and proficiency testing samples, they may be able to meet some of the competency requirements.

Slide 29. The CDC has published the PPM booklet that Alana had referred to. It is free for you to order or you can download it off the CDC website. In Appendix D, there are some good examples and instructions on how to perform and document competency assessments. The website also contains downloadable blank templates that you can configure to your own laboratory's testing menu.

Slide 30. Some examples of competency assessments are direct observations of specimen testing ensuring that all tests are performed during the patient's visit, or the correct microscope is being used, or that the testing personnel are performing the test as the laboratory policies and procedures state, and that the tests are – results are entered correctly in the patient's – patient or electronic medical record.

Slide 31. Some other things to look at are: Is the centrifuge and microscope being maintained and cleaned? And is the performance of these activities being documented? Remember, if it's not documented, it has not been done. These are only some examples of the competency procedures that can be monitored and documented. The free downloadable PPM booklet from the CDC has more examples as well as blank templates that you can use and adjust to your individual laboratory processes.

Slide 32. Some of the additional things you'll want to monitor are: Does the laboratory personnel maintain the laboratory environment to ensure that the workplace is clean and has sufficient lighting? Do you have an eye wash station? And are the staff documenting the testing of the eye wash station? Does the laboratory have and follow safety policy and procedures, such as proper disinfecting of the specimen testing and collecting areas, cleaning of the microscope? Does the laboratory personnel follow those policies? Does the laboratory follow state and safety requirements?

Slide 33. Again, in the CDC PPM booklet, there are further examples and templates how to create your individual monitoring logs. This booklet and its appendices also provide a guide to the applicable CLIA requirements.

Slide 34. A quality assessment plan is the backbone structure to ensure a laboratory is providing quality testing. Quality assessment starts with the risk assessment of all processes and procedures performed at the laboratory. Do you have procedures for each process and procedure the laboratory performs? And are they signed and dated by the current laboratory director? Are they current for what testing is being performed? If you have changed the testing procedure or stopped performing a test, did you update your policy and procedures to reflect that change? If you have updated your policies and/or procedures, you must retain the retired policy and procedure for 2 years. Can you retrieve your patient testing requisitions, reports, and maintenance records for the last 2 years? Again, these are only some examples of the quality assessment processes that may be monitored and documented.

Slide 35. Now, let's look at proficiency testing. The PPM lab must verify the accuracy of their testing at least twice annually. There are proficiency testing materials specifically developed for PPM laboratories that can be used to meet this requirement. If a laboratory does enroll in one of those P – proficiency testing programs, they are subject

to the proficiency testing requirements, including PT referral. Those proficiency tests could be utilized in competency reviews as well.

Slide 36. As you can see, documentation is key in a laboratory. So, documentation for the request of a test as well as the result must be maintained for 2 years and retrievable. Correct specimen identification, such as location or type of specimen collected as well as patient's two unique identifiers are important. The date of collection as well as the completed report, labeling and storage of reagents are also important; lot numbers, expiration dates, etc. Remember, transferring bulk solutions into smaller containers requires that the smaller container be labeled with the same information as the bulk container, including expiration dates.

Slide 37, Inspections. PPM laboratories are not subject to biennial inspections, although they may be subject to inspection if there is a complaint regarding the laboratory in regards to being operated in a manner that does not constitute a – that does constitute a risk to public health. To evaluate the complaint and to determine if the laboratory is testing beyond the scope of the PPM certificate, a survey can also be conducted in order to collect information on the appropriateness of PPM testing.

Slide 39. Under a PPM certificate, the laboratory may also perform waived tests. If waived tests are performed though, you must be sure to read the manufacturer's instructions and follow those instructions and recommendations. For waived testing, there is no Federal personnel requirement. Be sure to check with your state health department though to ensure that you are in compliance with any state regulations. Remember the states can require more stringent regulations.

Slide 40. The CLIA website provides additional information for waived testing. The CDC has also published a very easy-to-follow and free booklet called the "Ready? Set? Test!" booklet. It contains best practices for persons performing waived testing under a CLIA Certificate of Waiver or PPM laboratories that also perform waived tests. Along with the "Ready? Set? Test!" booklet, the CDC also offers online continuing education materials to assist with maintaining staff competency.

On Slide 41, we see an example of the "Ready? Set? Test!" booklet and an index of the materials it contains.

Summary

Slide 42. So to recap the key points that we have covered, a Certificate of Provider for Microscopy Procedure includes the nine specific microscopic exams. You must use a bright-field microscope or phase-contrast microscope. The exams are to be performed during the patient's visits, and the exams are performed by qualified individuals.

Slide 43. The PPM laboratory is subject to applicable CLIA requirements; proficiency testing or twice yearly test accuracy verification; record retention for at least 2 years; procedure manual that covers all the tests performed at that laboratory; and if microscopy testing is performed by an individual not meeting the PPM testing personnel requirements, the exams are considered moderate complexity so the laboratory would need to upgrade to a certificate of compliance or a certificate of accreditation.

Slide 44. Here we have listed the links to the websites mentioned in this presentation to assist laboratories to be able to access information regarding performing quality human testing under a PPM certificate.

Slide 45. CLIA has also published brochures to assist laboratories in interpreting the CLIA regulations. A very important brochure is Brochure number 7 that outlines the responsibilities of a laboratory director. Brochure number 8 provides guidance on performing proficiency testing and documentation. And Brochure number 9 is more for the public, but also laboratory staff or personnel who feel that testing is not being performed safely or correctly. Remember CLIA does follow up on all complaints. Another important brochure is CLIA number 10. This is assessing personnel competency. This brochure should be reviewed by every laboratory director.

Slide 46. If you have any questions regarding the information presented here today and other questions regarding the CLIA requirements, you can send them to the labexcellence@cms.hhs.gov. Please include the certificate type that you're asking the information in regards to, such as PPM, and our team of CLIA experts will respond to your questions. We will now open the presentation up to any questions from our audience.

Question and Answer Session

Nicole Cooney: Thanks very much. Throughout the Q&A session, we will ask webcast participants to provide feedback about their experience with the technology used today.

Remember to disable your pop-up blockers for best results. We will begin our session by fielding a few questions that we received from webcast participants, and we'll then alternate to questions from the phone. We'll also address some of the questions asked during registration.

Operator, could you please prompt the telephone users and begin to compile that Q&A roster?

Operator: If you would like to ask a question, simply press star then the number 1 on your telephone keypad. Again, that's star 1 for a telephone question. Please hold while we compile the Q&A roster.

Nicole Cooney: Okay. And while you compile that roster, we'll go ahead and start taking a few questions. Our first question is: How do I enroll in or apply to the CLIA Program?

You can enroll your laboratory in the CLIA Program by completing an application Form CMS-116 available online at www.cms.hhs.gov/clia or from your local state agency. Forward your completed application to the address of the local state agency for the state in which your laboratory is located. A list of state agencies is available at the CLIA website. If you are unsure as to how to complete the application, contact the state agency for assistance.

When applying for a certificate for provider-performed microscopy, you must have the name of the individual who will be the laboratory director and documents proving that individual qualifies to serve as the laboratory director. Laboratory directors performing nonwaived testing, including PPM, must meet specific education training and experience under Subpart M of the CLIA requirements.

Proof of these requirements for the laboratory director must be provided and submitted with the application. Information to be submitted with the application includes the CLIA numbers for other laboratories that the applicant directs, as applicable; verification of state licensure as applicable; documentation of qualifications, including education, copy of diploma, transcript from accredited institutions, CMEs, credentials, and laboratory experience. Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the

United States. Failure to submit this information will delay the processing of your application.

Our next question is: Please provide instructions for test counting for PPM examinations.

For microscopic examinations, count each as one test.

Our next question: I need help with billing. Where can I find the correct codes to bill for PPM testing?

CLIA provides oversight for laboratory testing. For questions specific to billing, you should contact your Medicare Administrative Carrier, or MAC. There are, however, lists of tests with their correct Current Procedural Terminology, or CPT, or Healthcare Common Procedure Coding System—HCPCS—codes on the CLIA website. At the CLIA Home page, click on the link for categorization of tests to access the page with these test lists available for download. The list of PPM examinations is on this page.

Okay. Our next question: Is there a field on the 1500 Claim Form to enter CLIA numbers?

Alana McCoy: Yes. Hello? Yes. The CMS 1500 Claim Form was just the health insurance claim form. There is a section on the form to fill out to place your CLIA number. That is Section 23. If you go on to the CMS website and on to Regulations & Guidance tab, you can find the instructions on filling out a CMS 1500 Form.

Nicole Cooney: Thank you. Our next question is: Aren't Washington and New York states exempt from CLIA? What does this mean? Do the PPM regulations apply in these states?

Fran Lehr: Yes. My name is Fran Lehr, and I am a laboratory surveyor and consultant in the State of Washington Region 10 Office. And the answer is – the question is – yes, these are – New York and Washington are exempt states, but the CLIA regs apply, and – which means that they do give out certificate of a PPM to those entities or providers applying for that category of license. With the Washington State, they have added the naturopath as an eligible provider to read PPMP. And Washington State does have a certificate of PPMP. Thank you.

Nicole Cooney: Thank you. Are nurse practitioners or physicians' assistants eligible to perform PPM?

Julia Appleton: Hi. My name's Julia Appleton, and I work at Central Office in CSM – yes, at CMS, excuse me. Okay. And the question is –answer is yes. So to review, to have testing personnel so that the person's performing the PPM, you have to have all of the degrees that we mentioned—the M.D., the D.O., the D.D.S., etc. And included in that group is the midlevel practitioner, so we have nurse practitioner, midwife, and physician assistant. Thank you.

Nicole Cooney: Our next question: Can nurse practitioners-owned practices apply for PPM certificates?

Julia Appleton: So both the nurse practitioners are also eligible to be laboratory directors for signing up for a PPM certificate. So the answer is yes.

Nicole Cooney: Thank you. What two tests are not considered PPM?

Daralyn Hassan: Good afternoon. This is Daralyn Hassan in CMS Central Office. The two tests that were mentioned are the Tzanck smear and the Gram stain. But bottom line is that the list of PPM examinations is given on the CLIA website; it was also given in this presentation. If the test that you're concerned about is not on that list, it is not categorized as a PPM exam.

Nicole Cooney: Thank you. Our next question: Do PT/INR fall under PPM exams?

Daralyn Hassan: Good afternoon. This is Daralyn Hassan again. No, the PT/INR testing can be classified as either waived or moderate complexity. We gave the website for the FDA's test categorization so that you can look on that website to see which – for the test that you're performing, which test categorization that test has been assigned.

Bottom line is if you have a certificate for PPM, you can perform the microscopic examinations and waive testing. If you are performing PT/INR, then it has to be the waived PT/INR.

Nicole Cooney: Thank you. The next question comes from a registrant. Does the provider performing the microscopy need certification in a particular specialty, for example, urology?

No, CLIA requires the testing personnel in a laboratory with a certificate for provider-performed microscopy to be a physician—M.D., D.O., or D.P.M.; midlevel practitioner; or a dentist—D.D.M. or D.D.S. There are no medical specialty requirements. In CFR 493.1363, each individual performing PPM procedures must possess a current license issued by the state in which the laboratory is located, if the licensing is required, and meet one of the following requirements: be a physician as defined in 493.2, be a midlevel practitioner as defined in 493.2 under the supervision of a physician or an independent practice if authorized by the state in which the laboratory is located, or be a dentist as defined in 493.2 of this part.

Going back to the webcast participants, my next question is: Can a nursing assistant working in a doctor's office perform urinalysis?

Daralyn Hassan: Good afternoon. This is Daralyn Hassan again. A nursing – it would depend on the nursing assistant's qualifications, but the bottom line is, if the nursing assistant does not meet the qualifications to perform – by urinalysis, you mean microscopic urinalysis? If the nursing assistant does not meet the qualifications to perform moderate complexity testing or meet the qualifications for PPM testing, then the answer is no. As far as dipstick urinalysis, which is waived, then, yes, a nursing assistant can perform dipstick urinalysis.

Nicole Cooney: Thank you. Our next question is on safety and environmental. Are eyewash requirements specific for PPM certificates? Or are they required for all testing levels?

Julia Appleton: Hi, this is Julia Appleton again. When it comes to safety and environment concerns, the PPM certificate does not have specific requirements. To get health, safety, and environment of care, you want to turn to your – look at your facility requirements and also the state in which you're in, which will define what would be the safe practices for the clinical unit that you're functioning in. Thanks.

Nicole Cooney: Thank you. Our next question: What are the options if you don't use PT or can't find PT materials?

Daralyn Hassan: Good afternoon. This is Daralyn Hassan again. If you don't use PT materials, the lab – a PPM lab is required to perform a twice annual verification of accuracy of the test. So you would have to determine a way in which you can either peer review, in which you can verify the accuracy of the testing that you performed. The PT materials are really, you know, pretty easy – generally pretty easy to use because they can – multiple people can read them and there's a prescribed answer. But otherwise, then one person maybe can read the slide and, before it dries out, have a second person, if there are multiple people in the practice, read that same slide and with a predetermined range of acceptability for results. So just some examples; the PPM booklet by CDC has other good suggestions.

Nicole Cooney: Great, thank you. Next we'll take a question from the phone. Operator, who's first in queue?

Operator: Yes, your first question comes from the line of Susan Khalil.

Susan Khalil: Hi, yes, thank you. It was a great presentation. But I do have a question because this proficiency testing, when I called our contact in Connecticut, he said we just needed to do it once annually, which is what they had just said was get a slide and have all the providers read it and make sure that there's consensus, that everybody's reading the same slide and identifying the same thing. But you're saying that it should be done twice a year, or could it be another type of proficiency where, you know, we're checking – you know, doing an audit, that, – you know, where that the order was documented, the machine is cleaned accordingly, everyone's following procedures. Do you understand what I'm saying?

Nicole Cooney: Give us one minute.

Susan Khalil: Okay.

Leah Ferrier: Hi, this is Leah, and the last items that you mentioned, the monitoring of the microscope and …

Susan Khalil: Yes.

Leah Ferrier: Those are competency and quality assessments. Those are not performance proficiency testing.

Susan Khalil: Right.

(Crosstalk)

Susan Khalil: I'm just asking because I'm – I …

(Crosstalk)

Leah Ferrier: So, yes, you would have to perform it twice annually.

Susan Khalil: Okay, I'll just clarify that. Thank you.

Nicole Cooney: Next question please from the phone.

Operator: Your next question comes from the line of James Flores.

James Flores: Hi, my question has to do with rural health clinics, and I'm curious about if the providers here at the hospital that deals with the clinics, if they want to start doing their own, you know, testing microscopy stuff at the clinics, if the lab holds a higher certificate, would I still need to get a PPM certificate for the rural health clinics and have them do their proficiency and stuff there? Or would they fall under the laboratory at the hospital?

Nicole Cooney: Give us one minute.

James Flores: Okay.

Ann Snyder: Hi, thanks for waiting. This is Ann Snyder. I also work in Central Office. I can speak kind of personally to that experience. Really, I should tell you that it's really a discussion you need to have with your lab director and a business decision of his. If he wants to take – he or she wants to take responsibility for all of those providers under his

certificate, I have to say to you that there's a risk associated with that and that's for you to determine. But in my experience, I had all the laboratories who I was not directly connected with have their own provider-performed microscopy certificate. So you may want to consider that as an option. But I would start with having a discussion with your laboratory director and how comfortable he or she is with doing that. Is that a helpful answer to you?

James Flores: Yes, I think so.

Ann Snyder: Okay, hopefully that will give you a direction.

James Flores: Yes, thank you.

Ann Snyder: Thank you.

Nicole Cooney: Thank you. Our next question comes from a webcast participant. Can you identify where I can find the types of lab tests in each category?

Daralyn Hassan: Okay, yes, this is Daralyn again. That information is available on the CLIA website as stated in the presentation: www.cms.hhs.gov/clia. On the CLIA website, there's a link that says categorization of tests. If one clicks on that link, at the bottom of the page, there's a link to the list of PPM exams. There's also a link to the FDA's website where you can find all of the thousands of laboratory tests and the test categorization.

Nicole Cooney: Great, thank you. The next question is: Just to confirm, if you have PPM certification, you do not need a CoW?

Julia Appleton: Hi, this is Julia Appleton again, CMS Central Office. That's correct. When you have a PPM certificate, you can do both—the nine microscopy tests that we mentioned as well as the full range of waived testing. So a second CoW waiver is – a waived certificate is not needed.

Nicole Cooney: Thank you. Our next question, which of the websites listed will help with QC requirements? Not all of these tests have QC available. Leah, can you take that question for us?

Leah Ferrier: Yes, I can, thank you. The CDC free booklet has some good examples of how you could do this. As well as if you look at your manufacturer's inserts, they also have some information provided of how you can meet that requirement. Did you find that helpful?

Nicole Cooney: Thank you. Our next question: As a home visiting primary care practice, can a PPM site test at home and bring the sample back to the clinic lab?

Ann Snyder: Hi, this is Ann Snyder. So you're asking a question about actually moving the sample from one place to another, and we do mention in the presentation that these tests are – these nine provider-performed microscopy procedures are labile. So one of the requirements is that the testing must be performed near the patient or at the patient's bedside or in that close proximity to the patient. Because those specimens are labile and they don't last, they would not last the trip from the patient's home back to a clinic. So that would not be allowed. Thanks.

Nicole Cooney: Thank you. Our next question: Can you please explain the conditions that allow a not-for-profit lab to have a multiple-site CLIA certificate?

Daralyn Hassan: Yes, good afternoon, this is Daralyn Hassan again. That answer could be a bit complicated. So would you please send that question to the Lab Excellence mailbox? Reference that you attended the PPM webinar, and we can ascertain all of the components of your situation and respond accordingly. Thank you.

Nicole Cooney: Thank you. Our next question: Can an OB group use their PPM certificate in the office and in the hospital setting to take care of their patients for fern testing?

Daralyn Hassan: Okay, this is Daralyn Hassan again. Again as stated before, please – because that question has multiple parts, please send that to the Lab Excellence mailbox. That address is given in the presentation, and we can respond in full to that question. Thank you.

Nicole Cooney: Okay. My next question came in through registration. Where can providers get information on the environmental space and safety requirements for PPM laboratories?

There are CLIA requirements for space and safety in the Facilities Administration section, Subpart J of the CLIA regulations. It's up to the laboratory to determine how to meet the regulations within its own physical setting. The free CDC booklet titled Provider-performed Microscopy Procedures: A Focus on Quality Practices provides information, pictures, and additional resources on safety. The Occupational Safety and Health Administration has laboratory safety standards which are available at this website: www.osha.gov/SLTC/laboratories/standards.html. Again that's www.osha.gov/SLTC/laboratories/standards.html.

And, operator, I think we have one more question on the phone. Can I take that now please?

Operator: Sure. That question comes from the line of Janet Strauch.

Janet Strauch: Hi. Can you hear me?

Nicole Cooney: Yes, we can.

Janet Strauch: Okay. I am in a high complexity hospital laboratory and we have a couple of different areas that would like to perform physician-provided microscopy. And from what I'm gathering, it would make more sense businesswise for them to be their own director of their own sites but then maybe work with the laboratory to make sure they're meeting all of their requirements. But I guess my question is, with regards to what actually has to be maintained at each location would be a procedure manual of just the procedures that they do, they don't have to copy all of the QA and all of those procedures that, like, a separate, moderately complex lab would have to have. They just basically need what procedures they're doing, a QA process proficiency, and QC. And I mean they don't have to have everything like a regular, moderately complex procedure manual would need. Is that correct?

Ann Snyder: Hi, this is Ann Snyder. It sounds to me like, from what you described, that you're heading in the right direction. So if you opt to have all of those locations under their own certificates, they need to stand alone.

So make sure that, if you are going to share procedures—I completely understand that—that, you know, like the heading at the top of the procedure, you know, or there's some place that notes that that procedure is for that CLIA number or that location.

Janet Strauch: Okay.

Ann Snyder: So, yes, so what you have described—it sounds reasonable to me.

Janet Strauch: Okay, all right, thank you.

Ann Snyder: You're welcome.

Nicole Cooney: Thank you. Our next question comes from a webcast participant. If a laboratory is CLIA-waived and performs KOH wet mounts, is a PPM certificate required?

Julia Appleton: This is Julia Appleton at CMS. And, yes, you would need to have a PPM certificate because you have – if you choose to perform even one of those nine microscopic tests that's classified as PPM, you would need that certificate and you would need to have the laboratory director qualified per our webinar today, and those requirements are on the website as well. And the testing personnel, the individual who's actually doing that KOH, would have to meet the testing personnel qualifications. Okay, I hope that helped. Thanks.

Nicole Cooney: Thank you. Our next question: Can a nonclinical staff member be a laboratory director for a waived laboratory?

Daralyn Hassan: This is Daralyn Hassan. Yes, yes, yes, they can. There are no educational or experiential requirements for a director for a certificate of waiver laboratory.

Nicole Cooney: Thank you. Our next question: If the test is not considered PPM, what kind of testing is it considered? Specifically, I'm thinking about synovial fluid examination for crystals using a polar – hold on, it's continued—using a polarizing microscope by department physicians? In addition, I want to make sure I'm following all regulations. Do you recommend any literature similar to what you've shown for PPM to make sure I am following all regulations?

Ann Snyder: Okay, this is Ann Snyder. There's a couple of questions in that – so there's a couple of questions there. First, I'll address the synovial fluid. So, synovial fluid examinations are considered high complexity. So if you're in a physician's office—I don't know your situation—but if you're in a physician's office practicing and you want to look at your own crystals, then you're going to need to get either certificate of compliance or certificate of accreditation.

Now, sometimes, if you're in a hospital or a health care setting where you are a physician and you can bring the crystal sample over to the laboratory, they can perform the testing for you. But be mindful that if you are a physician, a solo practitioner or in a group practice—whatever the situation—and you want to look at crystals in your office, then you'll need to get the appropriate certificate.

Now, I need to ask you this, Nicole, to read the other part of the question.

Nicole Cooney: Sure. In addition, I want to make sure I'm following all regulations. Do you recommend any literature similar to what you've shown for PPM to make sure I'm following all regulations?

Ann Snyder: Okay. So if you're talking about high-complexity and moderate-complexity testing, then we would refer you to our CLIA website. Take a look at our interpretive guidelines. On the left side of the page—on the main home page—there is an index, and you can take a look to find our clear regulations there. If you're talking particularly about a waived type of test, in the presentation, we gave you the example of the "Ready? Set? Test!" booklet.

The CDC also has another test booklet called To Test or Not To Test. That'll help you decide if that's – if the testing you want to perform is really appropriate for your setting. We really encourage you to go to the CDC website and look for that "Ready? Set? Test!" booklet or that PPM booklet. They're very helpful. If you're not familiar with waived testing, think about taking that online course that we recommend. And certainly if we can assist with you in any other way, we have brochures on our website, we have the interpretative guidelines, we've offered you the Lab Excellence mailbox as a source for us to answer questions. So feel free and comfortable, please, to send any questions you have to that website, and one of our subject-matter experts will respond.

Nicole Cooney: Thank you.

Ann Snyder: Thank you.

Nicole Cooney: Our next question: Are nurse practitioners and physician assistants able to do Tzanck?

Daralyn Hassan: This is Daralyn Hassan. If nurse practitioners and—what did you say—physician's assistants …

Nicole Cooney: Yes.

Daralyn Hassan: … meet the criteria for high – that's – those – it's high-complexity testing – for high-complexity testing lab director, then, yes, they can. So the requirement for high-complexity testing laboratory director is found in the CLIA regulations. On the CLIA website, there's a link for the interpretative guidelines, which would include the regulations. So you can look it up there and see if they meet those requirements, then yes; if they don't, then no. If – and also with regards to performing Tzanck smears, a laboratory needs a certificate of compliance or a certificate of accreditation. This is not PPM testing. Thank you.

Nicole Cooney: Thank you. Our next question: If you are a multispecialty group and only one physician is designated director for the PPM, can other physicians within the group do PPMs under that one certification?

Daralyn Hassan: So, this is Daralyn Hassan. Yes, as long as they qualify to being PPM testing personnel, then sure.

Nicole Cooney: Thank you. The next question is for me. Will the Q&A section of this presentation be transcribed and sent to participants?

This is Nicole Cooney. We are transcribing the entire event, and we will post an audio recording and the transcript on our Call Detail Page. And that is – I'm trying to think where – the best way – after – we'll be emailing all registrants after the event is over with a link to our evaluation, and there'll also be more information on how and where you can locate the audio recording and written transcript once it's posted. It does take

about 7 to 10 business days for us to get that up on the website. And keep in mind, we lose a business day with the upcoming July 4th holiday. So we will have that posted, and we will also be notifying the availability of that in the MLN Connects newsletter once it's out.

Next question: Does a person with a BSMT or master's degree qualify to be a lab director for a PPM lab?

Julia Appleton: Hi, Julia Appleton again. The answer to that would be no. To be qualified for a lab director, for a PPM lab, you need to have a medical degree; a degree of doctor of osteopathy; you have – you can have a D.P.M., which is podiatry medicine, I believe; midlevel practitioner, which would be nurse midwife, a nurse practitioner, or a physician assistant; a D.D.M., Doctor of Dental Medicine, or D.D.S., Doctor of Dental Surgery. Those are the only individuals who are qualified to hold a laboratory director on a PPM certificate. Thank you.

Nicole Cooney: Thank you. The next question: If a lab has a certificate of compliance, do they also need a PPM?

Daralyn Hassan: Hi, this is Daralyn Hassan again. No, they would not need a certificate for PPM. The certificate of compliance is more inclusive. It allows them to do a wide variety of tests as long as, when they apply for that certificate, they apply it for the appropriate test specialties.

Nicole Cooney: Thank you. Our next question comes from a registrant. Please speak about competency assessment in PPM laboratories.

Competency assessment is required for individuals performing PPM testing. At a minimum, the PPM lab must have a policy for competency assessment and perform and document it according to their policy. Some things to consider: Is the test actually performed during the patient's visit? Is the correct microscope used—bright-field or phase-contrast? Is the patient's specimen processed correctly and timely? And did the midlevel practitioner perform the test and report results according to the laboratory's standard operating procedure.

Our next question: Are there any training or competency requirements for waived testing? I don't see this in the "Ready? Set? Test!" book.

Daralyn Hassan: Hi, this is Daralyn again. Waived testing only has (three) requirements: to apply for the CLIA certificate, pay the applicable fees, and follow manufacturer's instructions. So, no, there are no requirements for competency and training in a certificate of waiver lab. It's good lab – it's always good lab practice, but CLIA is minimal standards, and so it's not required.

Nicole Cooney: Thank you. At this time, we're waiting for some additional questions to come in. Please remember that, if you have a question for us, you can type it in. And, operator, could you please reprompt on the phone?

Operator: Certainly, if you'd like to ask an audio question, simply press star 1 on your telephone keypad. Again, that's star 1 for an audio question.

You do have a question on the phone line from Marla Lyons.

Nicole Cooney: Hi, what is your question?

Operator: Marla, your line is open.

Marla Lyons: Okay, I have a twofold question. Earlier in the presentation, you mentioned that laboratory director of a PPM has to have laboratory experience, and I just would like to know where that is documented about the experience.

And also, if a PA is not allowed to practice individually in a state, would that disallow him to be the director?

Nicole Cooney: Leah, could you take that question for us?

Leah Ferrier: Could I have it repeated again?
Marla Lyons: In the early part of your presentation, under laboratory director, you mentioned lab – laboratory experience, and I would like to know where that is documented—that a physician or a midlevel practitioner has to have laboratory experience to be a director.

Leah Ferrier: I believe the experience is referring to as a physician, but I would have you send that into the Lab Excellence website, referring to this presentation, and we could give you further information there.

Marla Lyons: Okay. My second question was: If a PA is not allowed to practice individually in a state, does this – is he still qualified to be the director?

Leah Ferrier: According to the regulations that we presented earlier, no, he would not unless he was working in a Federal facility that does not require state licensure.

Marla Lyons: Thank you.

Nicole Cooney: Okay, we have another question from a webcast participant. The five-clinic limit—does this mean the director can oversee no more than five clinics? Or does it mean that the lab director can be associated with up to five CLIA certificate numbers higher than a waived certificate?

Daralyn Hassan: This is Daralyn. There is no five-clinic limit. The limit is five CLIA certificates for lab director with regards to nonwaived testing. And nonwaived testing includes the certificate for a provider-performed microscopy procedure. If you have further questions regarding this, please send that to the Lab Excellence mailbox. Thank you.

Nicole Cooney: Thank you. And Daralyn mentioned something that I wanted to let everyone know. We did receive a couple of questions that we're unable to take over the phone. There may be more specifics, more research is needed.

And so if you typed in a question and we were not able to address it on the line here, on slide 46 of the presentation, that's where you'll find the Lab Excellence mailbox. And that is labexcellence@cms.hhs.gov. Again, that's labexcellence@cms.hhs.gov. And we have time, operator, we can reprompt one more time for questions on the phone.
Operator: Again, if you'd like to ask an audio question, simply press star 1 on your telephone keypad.

There are no audio questions at this time.

Nicole Cooney: All right, well, that's all that we have for today. Again, if we were not able – okay, hold on – oh, we have one more question just came in.

Okay, wet preps and vaginal smears are considered PPM tests. Is – certification is required?

Daralyn Hassan: This is Daralyn. A CLIA certification is required in order for the appropriate individual to be able to perform those tests. So, yes, CLIA certification is required. Depending on your level of education and experience, they can be performed in a laboratory with a certificate for PPM or a laboratory with a certificate of accreditation or a certificate of compliance. Thank you.

Nicole Cooney: We have one more question. When will we get the AAPC credit?

I think I might know what you're referring to—certain national associations accredit Medicare Learning Network events. We do have some more information that you can view on our website. You will want to go to the MLN Homepage. Hold on one minute. I'm just trying to get the right address. It's probably easiest to send you to www.cms.gov/npc; that's Nancy – N as in Nancy, P as in Paul, and C as in Charles. And if you go there, you can find the date for today's call, June 28th, and you'll see CLIA Certificate of Provider-performed Microscopy Webcast. And if you click on that, there'll be more information on how you can obtain credit or seek credit from your professional organization. You have to go through the association. CMS did not accredit this event. So I hope that answered your question.

Our next question: We are a dermatologist's office, and all we do are KOHs. Is there anything specifically we need?

Daralyn Hassan: This is Daralyn. If you don't already have a CLIA certificate, then, yes, you do need a CLIA certificate to perform the KOH test. You can contact your state agency to get information on how to apply for CLIA certificates.

Additional Information

Nicole Cooney: All right. That does look like all of our questions for today. As we mentioned, if we were not able to address your question on the line, you may send it to labexcellence@cms.hhs.gov.

On slide 48 of today's presentation, you'll find information on how to evaluate your experience with today's call. We'll also push out the link to the evaluation to our webcast participants right now. Evaluations are anonymous, confidential, and voluntary.

But we hope you'll take a few moments to evaluate your experience with today's event. As a reminder, disable your pop-up blockers for best results.

I'd like to thank our subject-matter experts and all participants who joined us for today's MLN event. Have a great day, everyone.

Operator: This concludes today's call. Presenters, please hold.

-END-


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