HRSA Health Center Program

Audio file

Recording - Federal Tort Claims Act Site Visit Training for Health Centers.mp4

Transcript

Patricia Breen

Welcome to today's presentation. My name is Patricia Breen, and I am the Patient Safety Risk Management team lead in the Federal Torts Claims Act program in the Bureau of Primary Health Care. The team is pleased that you have joined us to learn about the FTCA site visit process. The Health Resources and Services Administration conducts health center FTCA program site visits to confirm compliance with programmatic requirements, in particular with respect to credentialing and privileging, risk management, claims management, quality improvement, and quality assurance. FTCA is dedicated to continuous quality improvement and has utilized feedback from health centers, reviewers, and staff to refine this year's site visit experience. Please enjoy the webinar, and thank you for the work you do each day to provide accessible, affordable, comprehensive, high quality primary health care. And I'll turn the program over to Leisa.

Leisa Niggel

Good afternoon everyone. My name is Lisa Niggel. I am employed by Kepro, and I will act as a moderator for this webinar. Next slide please. First, I would like to review some housekeeping items. Turn up the volume, so you can hear the presenter. Everyone was placed on mute upon entry. Use Q&A to submit questions during or after the presentation. The Q&A icon can be located at the bottom of your screen. This session will be recorded. Please complete the survey that will be sent via email after the presentation. A PDF of the slide deck will be provided after the survey is submitted. A certificate of attendance will also be provided after the survey is submitted.

Next slide please. The following topics will be discussed during today's presentation: FTCA site visit purpose, virtual site visit overview, site visit selection criteria, FTCA site visit rules and responsibilities, site visit process, FTCA site visit activities and areas for review, and FTCA site visit report. Next slide please. This slide shows the learning objectives for the webinar. After the presentation, you should be able to describe the FTCA site visit purpose, overview, and selection criteria, highlight FTCA site visit processes to promote understanding and compliance, identify elements required to achieve compliance with FTCA programmatic requirements, and review the health center response to the site visit report findings. Next slide please. It is now my pleasure to introduce the speakers for this webinar. Denise Watson-Haye serves as a nurse consultant for BPHC on the Patient Safety Risk Management team. As a nurse consultant, she is the site visit program lead who coordinates annual site visits and selections of health centers and provides oversight and technical assistance for deemed health centers. Miss Watson-Haye has over 20 years of nursing experience in quality management, critical care, medical-surgical nursing, telemetry, mental health, and long-term care. Miss Watson-Haye has a Master of Science in Nursing Leadership and Management and Nursing, and she holds certifications in legal nurse consulting, 6 Sigma, and healthcare analytics. She is a member of Sigma Theta Tau International and the American Society for Health Care Risk Management.

The second speaker will be Mary Coffey. Ms. Coffey is a registered nurse with a Masters degree in Health Care Administration. She has served in multiple capacities in the healthcare industry for 35 years, including CEO of federally qualified health centers. For the past 11 years, she has been an independent consultant, participating in operational and FTCA site visits and review of FTCA applications. I will now hand the presentation over to Denise, who will be the first speaker.

Denise Watson-Haye

Thank you so much, Leisa. Good afternoon everyone, and thank you for joining us. My name is Denise Watson-Haye. As Leisa mentioned, I am the Program Lead for FTCA site visits. Welcome. Let's begin. To give you a background, through the Federal Tort Claims Act, eligible HRSA-supported health centers may be granted medical malpractice liability protection with the federal government acting as their primary insurer. To receive coverage, grantees must submit an initial deeming application to the US Department of Health and Human Services, Health Resources and Services Administration, Bureau of Primary Health Care and meet the requirements to attain deemed status. Renewal applications for redeeming must be submitted on an annual basis to continue coverage in the FTCA program.

A deemed health center, its employees, and eligible contractors working within the approved scope of project are considered federal employees and are immune from lawsuits for medical malpractice. The medical, sorry, the federal government assumes responsibility for costs related to a claim resulting from the performance of a medical, surgical, dental, or related function. There is no cost to participate in health centers or its provider. Next slide please. So why do we conduct site visits? FTCA site visits are a critical part of the oversight and compliance process. First, it conducts site visits to support its responsibility to ensure compliance with the FTCA deeming requirements, with particular respects to credentialing and privileging, risk management, quality improvement/quality assurance, and claims management.

First, it conducts scheduled site visits throughout the year and may conduct urgent site visits if there are any matters that may occur during the calendar year. Site visits are distinct. FTCA site visits are distinct from health center program operational site visits under Section 330 of the Public Health Service Act. FTCA site visits enable HRSA to objectively assess and verify the implementation of the FTCA deeming requirements and provide technical assistance to health centers as needed and appropriate. The health centers that are currently FTCA deemed or applying for initial FTCA deeming may also be assessed during an OSV for compliance with FTCA program requirements for credentialing and privileging, risk management, claims management, and quality improvement and assurance for deeming requirements. So the purpose of the FTCA site visit is to identify and address noncompliance issues, provide technical assistance, and provide an objective to performance improvements for the health centers.

Next slide please. The site visit process begins with the selection of the health centers. In the past two years, HRSA had to take steps to modify the process to ensure health centers are meeting the FTCA deeming requirements. We have conducted site visits virtually, but that may change depending on current restrictions and guidelines. The health centers will be notified and aware if the site visit will be conducted virtual or on site. Whether the site visits are on site or virtual, the health center can expect the site visit team to conduct document reviews, staff and board interviews as well as facility tours. FTCA site visits are generally conducted within three days, and all details are discussed prior to the site visit during the pre-site visit call, which you will hear more about later on in this

presentation. The team consists of one to two federal representatives, depending on the size of the health center, and two contractors/consultants that are selected based on their areas of expertise.

FTCA staff will be in attendance and will serve as the subject matter experts on the FTCA policies and requirements. The site visit team will review their agenda with the health center and confirm times for interviews for key staff members. Next slide please. The selection process each year begins at the end of the deeming cycle. The reasons for site visit selections may vary depending on the sites that are selected. Selections could be related to the deeming application that was submitted and may have inconsistencies, or it could be related to the health center's professional liability claims. These factors that are listed may be the reason for health centers to have been selected for a site visit. So let's just go over them very quickly. Factors that may prompt a site visit may include, but are not limited to, the initial deeming applications, the submission for an FTCA redeeming application which demonstrates possible noncompliance issues with the FTCA program requirements or any other concerns, the need for follow-up based on prior site visit findings or other identified issues, history of medical malpractice claims, or the health centers at times may request for a site visit. The site visits will conduct a thorough assessment and provide analysis of findings by the end of the site visit.

HRSA has already selected the site visits for this year, for 2022, that will receive a notification anticipated at the beginning of May or no sooner than the last week in April. Health centers that participated in last year's site visit actions will be closed out prior to the start of the deeming cycle. We have used the past year as a learning opportunity to improve our site visit processes. So I do thank you all for your patience, as the site visit process was slower than usual. Thank you for all the service that you provide to the communities, and now I will turn the presentation over to Mary Coffey.

Mary Coffey

Next slide please. Thank you, Denise, and good afternoon to our amazing health center attendees. We so appreciate that you're here today, and we're hoping that we leave you with a few tidbits to get you ready. From experience, I know that once the health center has been selected for the FTCA site visit, it's natural to wonder what's going to happen next, and so this portion of the presentation will help you prepare for an FTCA site visit. Let's begin by introducing you to the site visit team and their roles and responsibilities. Next slide please. The FTCA site visit team, as Denise mentioned, consists of FTCA representatives and consultants. The FTCA representatives lead and provide oversight to the site visit team, provide programmatic guidance, and address any other issues that may arise during the site visit. The consultants evaluate the health center's compliance with programmatic requirements and provide technical assistance as needed in consultation with the FTCA representatives.

Next slide please. The health center is also part of the team and has responsibilities. These include providing requested documents, participating in the pre-site visit conference call, confirming staff is available to participate in the interview sessions and document reviews, inviting board members to the entrance and exit conference and to the designated board meeting, and arranging meeting space and internet connectivity. Next slide please. Speaking of internet connectivity, you may be wondering what programs and platforms are used during the site visit. Next slide please. The technology used includes Citrix ShareFile and GoToMeeting. Citrix ShareFile is used to upload files and affords access to all the documents needed for the visit. Naming conventions should be used to ensure that files are uploaded correctly. The GoToMeeting platform is utilized for video conferencing during virtual site visits and

encompasses all aspects of the visit including the pre-site conference call, the virtual tour as we mentioned, entrance and exit conferences, board meetings, and meetings with staff. Next slide please.

The site visit process consists of four phases: the pre-site visit planning, the pre-site conference call, site visit review, and site visit report. Each of the phases will be addressed in the following slides. Next slide please. The pre-site visit planning and pre-site visit call are activities that occur prior to the team arriving on site. Pre-site activities are critical components of the process with the ultimate goal being a successful site visit. There are many benefits to planning before a site visit, such as assisting in decision-making on how to get the work done before you get started on it, facilitates better allocation of your resources, your scarce resources, prioritizes tasks by deciding beforehand what's important, and leads the way towards teamwork and cooperation. In summary, with a clear plan in place, you can focus on the tasks and assignments that are the most important for the site visit rather than trying to waste valuable time and energy figuring out what needs to be done next.

During the pre-site visit planning, the health center is notified of its selection for site visit through EHB, which is the electronic handbook. The health center confirms site visit participation by e-mail to HRSA and is typically given three to five days to confirm participation. The initial contact by the FTCA representative is to set the date for the site visit and send the pre-site readiness tool and the document list. Thereafter, contact with the health center will be made by the consultants, beginning with the lead consultant, who will send a notification letter and provide additional documents. Details regarding the notification letter are as follows. Next slide please. The notification letter is typically sent between five to eight weeks prior to the scheduled site visit. The letter will include names, roles, and contact information for the site team, a sample agenda, which may be in a draft format, details and logistics regarding the pre-site visit call, requested documents listed by area of review, such as risk management, credentialing and privileging, and three proposed dates and times for the pre-site visit call, which brings us to the second pre-site visit activity. Next slide please.

The purpose of the pre-site visit call with the health center and the site visit team is to introduce the site visit process, clarify roles and responsibilities, and outline the site visit logistics. Next slide please. A key component of the call is to review and discuss the site visit agenda. The goal is for the site visit team and health center to work collaboratively to produce a final agenda. The agenda is created based on a standardized template that is utilized for all site visits and from the recommendations and availability of staff submitting by the health center. The standardized template will provide start times for all meetings and GoToMeeting login information. The health center will edit the draft agenda by making any changes to the base of the template, such as rescheduling the tour, selecting an hour time slot for the team to meet with the governing board members, inserting names, titles, and contact information of staff members that will be in attendance during the scheduled interview sessions, advising the site visit team of any staff members with limited availability, and offering alternate times. The final agenda will be emailed and uploaded into Citrix ShareFile three days prior to the scheduled visit.

This completes the pre-site planning phase, and we will now shift to the site visit review phase, otherwise known as show time. Next slide please. Once the pre-planning logistics have been completed and the required documents have been uploaded, the health center will focus on the site visit review logistics. Next slide please. The keys to successful site visits, meetings, and interviews include health center staff and board members active participation and key management staff participation in all site visit activities, and we define key management staff. That would include the Executive Director, Chief

Executive Officer, whatever the title is, and the same for all of these titles, whatever this individual is called in your facility, Chief Medical Officer, Human Resources, or other staff for credentialing and privileging, staff responsible for QI/QA, and Risk Management, Claims Manager, and other staff the health center determines has an integral role in any of the areas that we that will be reviewed by the site visit team. It is not appropriate for the Health Center Counsel or Primary Care Association representatives to attend meetings and interviews.

The FTCA site visit should not be recorded. Additional keys to successful meetings and interviews continue on the next slide. Next, there we go. So you're going to be prepared to participate in the entrance conference, which includes staff introductions, a review of the agenda, including any updates and/or logistics that occurred since the agenda was uploaded, and a general organizational overview presentation by the health center. Interviews and meetings will be conducted with the health center, and this will include a review of documents. The exit conference will include the preliminary findings by the health center team. In addition, the health center executive should prepare the Board of Directors for a discussion during the board meeting sessions that will consist of oversight of applicable health center activities.

The Board of Directors meeting will be between the site visit team and board members. Keep in mind even though this is a compliance visit, this is your time to shine and showcase all the great things you are doing. Next slide please. Once the entrance conference has been completed, the clinical review aspects of the site visit begins. This consists of the virtual tour and a deep dive into the programmatic requirements for risk management systems, credentialing and privileging, quality improvement/quality assurance, and claims management. We will provide details regarding each of these processes in the next slides, and please remember you will get a copy of these slides after the site visit. So let's begin with the site visit tour. Next slide please. The site visit team will provide guidance on how to conduct the tour prior to the site visit. The tour will be conducted via GoToMeeting, and key clinical staff should be present to answer questions.

The frontline staff may also be requested to participate. In this instance, we define key clinical staff as nursing managers or directors, team leads, dental staff, optometry staff, pharmacy staff, et cetera. Of course, this again will depend on the size of your organization, and please know we recognize the health center wears many hats. Next slide. The site visit team will ask that you allow entry into a variety of areas, which may include any service areas included on form 5A, which is your personal approved scope of project. This slide provides some examples of areas that will be included in the tour but is not meant to be an exhaustive list. Let's go to the next slide, programmatic requirements. We will now delve into the four areas that will be reviewed for FTCA programmatic requirement compliance. This part of the presentation will include examples of documents that will be reviewed, specific program requirements, and opportunities to test your knowledge. Buckle up, you are 1/4 of the way through your site visit. Next slide please.

The first and most comprehensive programmatic review is in the area of risk management. While risk management encompasses the entire organization, the focus of the review is on clinical risk management. Clinical risk management is about minimizing risk and harm to patients by identifying what can and does go wrong during care, understanding the factors that influence this, learning lessons from your misses, adverse events, sentinel events, and clinically-related complaints and grievances,

ensuring action is taken to prevent recurrence, and putting systems in place to reduce risk. The overall goal is to be proactive rather than reactive. Next slide please.

Prior to the site visit and during the site visit, the site visit team will review the requested documents you have submitted. The first component to the review includes an analysis as to whether the health center documents submitted are in agreement with the programmatic requirements. Interviews will be conducted to discuss the documents and answer any questions you have. If needed, technical assistance will also be offered at this time. Documents included and discussed in the next slides are not exhaustive. Be sure to review the required document checklist by program requirement provided to you during the pre-site planning phase. Some of the documents reviewed during the risk management programmatic review will include a sample of five to 10 patient records that include clinic notes and/or a summary of care, patient satisfaction survey results, and we do not need every individual clinic results, a summary will suffice, patient complaints, grievances, policy and procedure as well as an active and resolved patient complaints and/or grievances log, and risk management training documents to include policies and procedures, training plans, sign-in sheets, and/or electronic logs. Next slide please.

The risk management training documents will also include procedures, training protocols, monitoring and tracking for infection control and prevention, such as blood-borne pathogens exposure protocols, infection control policies and procedures, hand hygiene training and monitoring program and other infection control methods to prevent communicable diseases, sterilization, and/or surgical practices. Examples are included on this slide, such as dental, OB/GYN, podiatry, and minor surgery. Please note if you have any of these programs on Form 5A, please be sure to include your protocols, and again, this list is not exhaustive. Medication management control and these policies, procedures, training, monitoring, and tracking would also include pharmacy, if applicable, and point of care testing equipment, such as glucometers, centrifuges, etc.

Documents typically omitted when reviewing this area are the training logs for each area of the review, so please add this to your list of things to make sure you have on hand. Next slide please. In addition, policies and procedures for documenting, analyzing, and addressing clinically-related complaints and grievances, sentinel events, adverse events, and near misses will be reviewed. Critical to this review will be evidence that demonstrates systems such as logs and spreadsheets are in place to track, trend, and analyze events as well as evidence that process improvements have been implemented. Regardless of who responds to these events, the risk manager should receive tracking and trending reports because these events may call attention to problems and provide opportunities for improvement. In addition, a claim or lawsuit may be prevented when the situation is resolved. In this arena, many times a reviewer does not receive evidence of sentinel events, adverse events, or near misses logs or defined processes included in the policies and procedures. So as we mentioned, the first step is to look at the policies and procedures, guidelines, whatever you have on hand, and then we will be looking to see if those processes were implemented and whether everything is in cohesion with the programmatic requirements, so the next slide please.

We're going to move on to risk management training, and while risk management training is mandatory and certain specific areas of high risk must be addressed in the training, health centers are otherwise given considerable flexibility in determining the content format and approach for the trainings. This is by design because effective risk management includes identifying the high-risk areas and activities for your organization and targeting those areas of risk with relevant training and education for all staff

appropriate to their job roles. HRSA does not require a specific course or courses to fulfill the requirement for risk management training. Next slide please. When the risk management training plan is reviewed, it is reported to note the consultants are looking for an annual comprehensive plan, not a list of training topics for the year. This annual plan should describe how the plan works and is implemented, the required trainings and sources utilized for training, and examples of sources again include but they're not exhaustive: ECRI, CDC, NAHC, AMA, and HRSA, levels of staff required to participate in each of the trainings and completion time frames, how the health center will track and document trainings to ensure completion, and enforcement and monitoring methods to ensure completion. Next slide please.

As noted in Chapter 21 of the Health Center Program Compliance Manual, the requirement states the health center has developed and implemented an annual healthcare risk management training plan for all staff members based on identified areas and activities of highest clinical risk for the health center including but not limited to obstetrical procedures and infection control and any non-clinical trainings appropriate for health center staff, including HIPAA medical record confidentiality requirements. Some examples of trainings might include continuing education for electronic fetal monitoring or dystocia drills for obstetrical procedures, blood-borne pathogen exposure protocols, infection prevention and control policies, hand hygiene training and monitoring, dental equipment sterilization for infection control and sterilization, HIPAA medical record, and then, of course, specific trainings for groups of providers that perform various services, which may lead to potential risk, and some of those services are dental, pharmacy, family practice. Next slide please.

Per PAL 2022-01, and this is the latest deeming application PAL, health centers that provide obstetrical services through health center providers need to include obstetrical training as part of their risk management training plans to demonstrate compliance. You might be asking why this is important to health centers, and what is meant by prenatal and postpartum? Start with definition. Prenatal care, quite simply, is the care you receive during pregnancy. It plays an important role in reducing frequency of maternal deaths, miscarriages, birth defects, low birth weight, and neo-natal infections. Postpartum care is the medical care that begins upon delivery of the infant and typically lasts six to eight weeks but can last up to a year. And now the why. As noted in ECRI's training, quality of action, obstetrical care part one before and after labor, community health centers cared for 552,150 pregnant women who access prenatal care. About 73% were seen in the first trimester and were more likely to have chronic illnesses such as hypertension, mental disorders, diabetes, and asthma than were patients of office-based physicians. The Centers for Disease Control and Prevention reports that severe maternal complications have risen 50% in the past decade. Two thirds of maternal deaths occur postpartum with cardiovascular complications, the leading cause of maternal mortality. Other common causes include hemorrhages, infections, and hypertensive disorders of pregnancy. Cardiomyopathy can develop weeks or months after giving birth, and diagnosis is often delayed or missed. Next slide please.

The risk management tracking tool should clearly demonstrate that all staff members, clinical and non-clinical, have completed all required trainings. Some examples of tracking tools include Excel spreadsheets and electronic learning tracking reports. These reports need to include training for each staff member. While summary reports can be useful, they do not provide evidence that all staff completed health center-required trainings. In addition, if all staff have not completed training per the health center's risk management training schedule, there should be evidence as to what remediation actions the health center implemented. So now let's take a little breath here and test your knowledge.

Next slide please. I'm going to read this scenario, and then I'll give you a few minutes to digest it, and then we'll move on to a polling question.

ABC Community Health Center has developed an annual risk management training plan. Hand washing and HIPAA training is provided each year for clinical staff. The charge nurse is responsible for providing the education, which includes a combination of one-on-one training with a return demonstration of hand washing technique. An article regarding medical record confidentiality is handed out, and staff are responsible to read it on their own time and complete 10 test questions. Staff have all year to complete the required training. Completion rates are reported to the Board of Directors. Obstetrics training is not included in the annual risk management training plan, as only prenatal and postpartum care is rendered at the health center, and labor and delivery services are not provided by health center employees. I will give you a few seconds here. Next slide please.

Please pull up polling question #1. Question #1: is ABC Community Health Center in compliance with risk management training requirements. Your response is yes or no, and again, we'll give you a few seconds here to respond. Well, please pull up the polling. Question response to #1: is ABC Health Center in compliance with risk management training requirements? The answer is no. Outstanding. Per PAL 22-01, calendar year 2023 requirements for Federal Tort Claim Act coverage for health centers and their covered individuals, health centers that provide obstetrical services through health centers, providers need to include obstetrical training as part of their risk management training plans to demonstrate compliance. This includes health centers that provide prenatal and postpartum care through health center providers, even if they do not provide labor and delivery services. Next slide please.

At this time, we will discuss the diagnostic referral and hospitalization tracking. Patient referrals are getting a close look because the process is not as thorough or efficient as it should be, which can lead to delays in diagnosis and treatment and other lapses in patient safety. This is an area of high organizational risk. Missed or delayed diagnosis is a common cause of medical malpractice findings in ambulatory care. The patient referral process cycle begins with the primary care provider's orders until the primary care provider communicates results and/or a plan to the patient and/or family. This is what is called or referred to as a closed loop process. Next slide please. The first step in assessing the health center's diagnostic referral and hospitalization tracking for compliance is by reviewing and assessing the health center's policies and procedures and tracking logs as well as conducting interviews with staff involved in managing the tracking processes. Next slide please.

Referral and hospitalization tracking procedures and logs will be reviewed, and interviews will be conducted to determine if a closed loop process is described and implemented. Tracking referral and hospitalization tracking procedures would demonstrate a closing process by clearly addressing time frames for follow-up, types and numbers of communications, individuals responsible for each step within the process, and documentation of all steps in the process. Next slide please. Diagnostic tracking procedures, logs, and laboratory agreements will be reviewed, and interviews will be conducted to determine if a closed loop process is described and implemented. Tracking procedures would demonstrate a closed loop process by clearly addressing abnormal and critical test results, time frames for follow-up, types and numbers of communications, individuals responsible for each step within the process, and documentation. So let's test your net knowledge. Next slide please.

This slide represents ABC Community Health Center's hospital admission emergency department visit tracking report. The health center provided a log for four patients, and the log included patient name,

date of birth, date of admission/emergency department, visit date, name of persons who notified the health center, reasons for admission, hospital records received or the emergency department's records received, and the date of office follow-up. Let's give you a few seconds to take a look at this submission, and then we will go on to polling question #2. Next slide please. Please bring up the polling question. Polling question #2: did the health center upload a complete and accurate hospital admission emergency department tracking report? Response is yes or no, and we'll give you a few seconds here to respond. Please pull up the responses to polling question #2, and the response, you are correct, is no. The hospital admission and ED visit tracking log was incomplete, and therefore, a closed loop process was not evident. In Chapter 21 of the Health Center Program Compliance Manual, it says you'll meet compliance with the FTCA requirements by providing documentation that you have identified and mitigated the healthcare areas and activities of highest risk within the health center's HRSA-approved scope of project. Next slide please.

Let's move on to the quarterly risk assessments. To meet this requirement, you need to demonstrate you have implemented and maintained an ongoing risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health-related litigation through completion of quarterly risk management assessments. Next slide please. Risk assessments should focus on areas that can potentially prevent or decrease the likelihood of medical malpractice claims. This would include patient safety and clinically-focused risk assessments. While important, non-clinical elements, such as building maintenance and parking lot inspections, will typically not result in claims related to medical malpractice. These risk assessments should be conducted on at least a quarterly basis, and when you've completed your assessments, you need to document your findings, identify areas of highest risk, and take action to improve the areas of highest risk. Your documentation that you submit should provide detailed information that allows a clear understanding of the methodology and outcome of your assessments. Next slide please.

Now we'll talk about the annual report to the board. To meet annual report to the Board of Director compliance, the health center should demonstrate again that it has implemented and maintained an ongoing risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health-related litigation, and an annual reporting to the health center board is required. Next slide please. To meet this requirement, the health center will demonstrate implementation and also their annual report. The annual Board of Director report should reflect a 12-month period of risk activities. Standalone minutes as evidence of an annual report to the board does not meet compliance. Non-clinical elements, such as building safety or maintenance, must not be the only topic addressed in an annual report. The report should primarily be focused on clinical elements of risk management and safety. Next slide please. The following elements in the annual Board of Director report are required: completed risk management activities, for example, risk management projects assessments, status of the health centers performance relative to established risk management goals, for example, data and trends analysis and including sentinel events, adverse events, near misses, falls, wait times, patient satisfaction information, and other risk management data points selected by the health center. It should also include proposed risk management activities for the next 12-month period that relate and/or respond to identified areas of high organizational risk and evidence that any related follow-up actions have been implemented. Next slide please.

Well, let's test your knowledge again. Next slide. ABC Community Health Center uploaded the past 12 months of meeting minutes reflecting completed risk management activities reported to and discussed with the Board of Directors. We'll give you a second. Let's pull up the next slide for a polling question.

Polling question #3: did ABC Community Health Center submission meet the annual board report requirement? We'll give you a few seconds to respond. All right. Please bring up the responses to polling question #3. Outstanding. The correct answer is no. Again, the report must be from the current or previous year reflecting activities over a 12-month period of time, and that's separate. Quarterly or monthly reports or minutes are not acceptable for this report. Next slide please. So we're going to briefly touch on the risk manager. In order to meet compliance, you must provide documents and examples of the risk manager's role in the organization, a job description that clearly details duties that would typically be conducted by the risk manager, and risk management training for the previous 12 months prior to the submission of your FTCA application. This concludes the risk management programmatic compliance overview, and we will now move to quality improvement/quality assurance. Next slide please.

Alright. To be in compliance with the programmatic requirements, the health center must have an ongoing quality improvement/assurance system that includes clinical services and clinical management and maintains the confidentiality of patient records. This would include a quality assurance plan, six months of QI/QA meeting minutes within the previous 12 months, samples of QI/QA projects, and data used in conducting QI/QA projects. Next slide please. It will also include clinical guidelines or protocols or other sources of evidence-based care, such as UpToDate or your EHR clinical decision-making support systems, provider peer review, health center bylaws, board meeting minutes, the most recent six months, and the governing board roster. In addition to looking at documents, as always, we will conduct staff interviews. On the slide are the typical components of a QI plan, so the statement of purpose. An example would be to support improved health care and healthcare delivery and outcomes. The scope of the plan would describe what the QI committee will do, administrative responsibilities identified by title, and the individual who has overall responsibility for the program. Risk management systems may be in their QI/QA plan or you may have a separate plan, role of peer review in QA program, frequency of review, and any process improvement actions, committee compositions, such as membership and meeting frequency, committee accountability. This would be where the board sets quality-related goals and monitors progress towards achieving the established goals that would be the board and key management staff, methods for conducting QI/QA activities such as PDSA, tracking of your QI/QA activities, and of course approval and review by the board. This plan does not have to be 20 pages as long as you have the required information. Next slide please.

The QI committee meetings will be viewed, and of course, you need to make sure that you have enough information in your minutes that document the implementation of the QI plan for the organization and include reports from your committee's peer review, information on monitoring of the measures that you're reviewing, subcommittee reports, which include and document results of the QI activities, baseline measures, interventions, and results of interventions with expected outcomes through monitoring. When you do submit your minutes, please make sure that the data is either recorded in the minutes or attachments are uploaded with the minutes that demonstrate the data. So let's test your knowledge. Next slide please.

ABC Community Health Center submitted its peer review policies and procedures, and discussion took place with its CMO and quality improvement director. The policy and procedure indicated that the health center would conduct periodic assessments of the appropriateness of the utilization of services and the quality of services provided. During the interview, the CMO indicated that peer review was conducted twice a year. Once again, we'll give you a few minutes to digest this, and then we will pull up the polling question. All right, please. Next slide please, and please pull up the polling question. The

polling question: is the Health Center in compliance with the Health Center Program Compliance Manual Chapter 10 requirements? Yes or no, and once again, we'll give you a few seconds to respond. Please pull up the polling responses, and this is correct. The answer is no. Two issues were noted in this scenario. The policy and procedure does not define periodic assessments, and the health center staff indicated it is not performing quarterly peer reviews. Next slide please.

Now we're going to move on to the third programmatic requirement, credentialing and privileging. According to chapter five of the Health Center Program Compliance Manual, the health center must utilize staff that are qualified by training and experience to carry out the activities of the center. Next slide please. During the site visit, the FTCA team will review documents and verify files. You're very familiar with this conduct. Interviews, and technical assistance will be provided if needed. The FTCA site visit team will request specific provider files for the review process, and the specific files that will be requested for review will be uploaded into Citrix ShareFile. Next slide please. The site visit team will review no fewer than 10 files for LIP and OLCP staff, those are your licensed independent practitioners and other licensed and certified practitioners, and no fewer than five files for other clinical staff. Please keep in mind that file limits may be altered based on the size of the health center and site-specific clinical staffing module.

The site visit team will also interview the staff responsible for credentialing and privileging maintenance and staff responsible for approving credentialing and privileging, such as the Board of Directors, the Executive Director, Chief Medical Officer, Chief Dental Officer, and/or Behavioral Health Officer, and again, this all depends on your hierarchy. The next slide please. And in addition, the site visit team will review form 5A, column two and three, to determine credentialing and privileging has been conducted, and you are in compliance with the requirements. Next slide please. So briefly, let's go over some definitions. Licensed independent practitioners, known as LIPs for short, are permitted by law and the organization to provide care and services without supervision and within the scope of their individual license and consistent with clinical privileges and HRSA's approved scope of service. Other licensed or certified healthcare practitioners, OLCPs, are individuals not permitted to provide patient care and services without supervision, and other clinical staff include individuals from whom licensure, registration, or certification are not required. However, they do conduct care within the health center. So for LIPs, we're looking at physicians, nurse practitioners, nurse midwives, etc. Other licensed clinical practitioners, we're looking at registered nurses, laboratory technicians, certified or registered medical assistants, or certified dental assistants. And with other clinical staff, some examples are medical and dental assistants and community health workers. Next slide please.

In preparing your files for credentialing and privileging, please be sure to include all of the initial and recurring credentialing elements. This includes for initial credentialing, government picture IDs, education and training, and for initial and recurring credentialing, current licensure registration certification, National Practitioner Data Bank query, DEA registrations, and BLS training. Next slide please. When reviewing policies and procedures and preparing files for privileging, please be sure to include the initial and recurring privileging elements. That would include verification of current clinical competence fitness for duty, immunization and communicable disease status, and contract cooperative agreements, if applicable, and this occurs for both initial and recurring. It should also include a delineation of privileges granted by the health center and/or hospital and a process for denying, modifying, or removing privileges based on assessment of clinical competence and/or fitness for duty, and this criteria applies to LIPs, OLCPs, and OCS staff. A brief note on temporary privileging in case of certain government declared emergencies or

disasters or as determined by HRSA on a case-by-case basis; deemed health centers can use an expedited credentialing and privileging process to ensure temporary FTCA coverage for health center provider during such emergencies. This process includes verification of identity, professional credentials and licensure, claim history, and other requirements. Please see PAL 2O17-07 for detailed information. Again, that's PAL 2017-07. Next slide please. We are again going to briefly test your knowledge. We'll go to the next slide please.

ABC Community Health Center uploaded its credentialing and privileging policies and procedures. The policy indicated BLS and verification of immunization and communicable disease occurred upon hire, and a National Practitioner Data Bank query occurred for LIPs upon hire and on a recurring basis. We'll let you digest that, and then we will ask a question. All right, let's go to the polling question. Polling question #5 and your last polling question is: does the health center's policy and procedure meet FTCA requirements and Health Center Program Compliance Manual Chapter 5 requirements? Your response is true or false, and we'll give you a few seconds to click those buttons. Let's pull up the responses please. That is correct. False is the answer. The health center's policy and procedure indicated verification of BLS immunization and communicable disease status occurred upon hire. However, this occurs on a recurring basis as well. In addition, the National Practitioner Data Bank Query occurred upon hire and recurrence for LIPs. However, there was no mention of the OLCP and OCS staff, which are also included in this process. The Health Center Program Compliance Manual Chapter 5 does state the health center would demonstrate compliance with this requirement by fulfilling all of the credentialing and privileging requirements. Next slide please.

All right, our fourth programmatic requirement is claims management. According to Chapter 21 of the Health Center Program Compliance Manual, the health center has a claims management process for addressing any potential or actual health or health-related claims, including medical malpractice claims that may be eligible for FTCA coverage. Next slide please. To determine compliance, the site visit team will review the health center's claims, procedures, list of current and previous malpractice claims, and the description of its process for reviewing malpractice closed claims. Per 2022-01 Claims Management 2A, it outlines the elements that should be included on the claims list. This list should be reviewed as you prepare for your site visit and as you complete your FTCA deeming application. The site visit team, as usual, will also interview staff responsible for claims management. Next slide please. Chapter 21 of the Health Center Program Compliance Manual stipulates the claims process ensures the preservation of all health center documentation related to any actual or potential claim or complaint, for example, medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinical operations, procedures, to name a few, and any service of process or summons that the health center or its providers receive relating to any alleged claim or complaint is promptly sent to the HHS Office of the General Counsel, General Law Division, per the process prescribed by HHS, and is further described in the FTCA Health Center policy manual. These requirements will be evaluated for compliance through document review and staff interviews. Next slide please.

When preparing information regarding the health center's professional liability history and history, the health center should provide a very brief description of the malpractice claim and what has been done by the organization to resolve the issue. One such example may include peer review conducted of medical records. For the claim conducted, the brief description of closed malpractice claim will include information about the provider or providers, specialty, date of occurrence, summary of allegations, and status or outcome of the claim. Do not include specific information about the claim in the application.

Next slide please. People often wonder, well, what is the definition of a closed claim? The definition according to the FTCA policy manual is that a closed claim will consist of any of the following: a settlement is reached, lawsuit is decided by a federal judge without a jury, or the case is dismissed with prejudice, which means one cannot refile the same claim.

We have concluded the third phase of the site visit and are ready to discuss the fourth and final phase of the FTCA site visit, the site visit report. Next slide please. The FTCA site visit report provides details of the final findings to be in compliance with the FTCA program regulations in the areas of risk management, credentialing and privileging, quality improvement and assurance, and claims management. Next slide please. HRSA will develop and share an FTCA site visit report with the health center, typically within five to eight weeks after site visit completion. The report will convey the site visit findings and determinations regarding the health center's implementation of FTCA deeming requirements. The FTCA site visit report will also be used to support programmatic decisions, identify risk and claims management findings that require follow-up and corrective action, and identify technical assistance needs for FTCA deemed health centers. Next slide please.

The site visit report will classify the HRSA FTCA compliance determinations for each element reviewed as no compliance issues noted or compliance issues noted. The health center will need to provide a written response to all compliance issues noted in the report. The report may also include performance improvement opportunities. However, the health center is not required to provide written responses to these suggestions. Next slide please. The health center site visit report will be sent to the health center and will be stored in EHB. HRSA will send action plans via each EHB as well. All actions required to come into compliance with programmatic requirements will be highlighted, and due dates will be provided. Health centers must respond and demonstrate compliance with FTCA programmatic requirements to maintain deemed status. Next slide please. Very briefly, we'll conclude by giving you some tips for a successful site visit. Review your policies and procedures, and make sure all elements are in alignment with the Health Center Program Compliance manual, the FTCA policy manual, and the Program Assistance Letters for the upcoming deeming year. Complete the agenda with names, titles, and contact information for all key staff members who will participate in meetings and interviews. Practice the virtual tour in advance to identify and resolve any problems with internet connectivity. Next slide please. Contact the lead consultant with questions regarding documents and time frames. Upload all required documents two weeks prior to the FTCA site visit into Citrix ShareFile, organize your credentialing and privileging files, documents by staff name, and upload as directed. Questions regarding documents and time frames should be clarified with the lead consultant. Thank you for your attention. Next slide please.

Leisa Niggel

Thank you, Mary and Denise, for very informative presentations. The following slides provide HRSA and other resources, including internet links, that will be helpful during preparation for an FTCA site visit. These slides will be available in the PDF version of the slide deck that will be provided after a post-webinar survey is completed. Next slide please. So we're going to provide you with HRSA resources for risk management training.

Next slide please. HRSA resources for credentialing and privileging. Next slide please. HRSA resources for claims management. Next slide please. HRSA resources for site visit report. Next slide please. We're also giving you slides with ECRI resources. Please note that you will need to be registered

on the ECRI website to access the resources noted on the following slides. So we're going to provide you with ECRI resources for risk management, ECRI resources for quality management, ECRI resources for credentialing and privileging. Next slide. ECRI resources for claims management. Next slide. And ECRI resources for obstetrics, infection control, and medication management. Before we move on to questions, I'd like to review some final reminders. Please take a few minutes to complete the post-webinar survey. A link to the survey will be provided in a follow-up email after the webinar. After the survey is submitted, you will receive an email with a certificate of attendance and a PDF of the slide deck. Next slide please. Now we will move on to questions. Again, questions can be submitted via Q&A icon at the bottom of your screen. Now a lot of the questions were answered during the webinar, but I'm going to pose the questions that are still iin the queue with Q&A. So the first question is: why can't visits be recorded? And Patty Breen is going to answer this question.

Patricia Breen

So that's a question that I would refer to our health center support line, if you would, just because there are nuances in that, and I think they can give you the best answer. I also, Leisa, I wanted to take this opportunity first of all to thank our speakers but also to make sure that everyone is aware. I think there's a little bit of confusion around who has to take obstetrical training, and so I did want to make sure that we made that part clear, that FTCA-deemed health centers that provide obstetrical services through FTCA-deemed providers need to include obstetrical training as part of their risk management training plans to demonstrate compliance, and that obviously includes any health centers that provide prenatal and postpartum care through FTCA-deemed providers, even if they don't do labor and delivery, so that one seems pretty obvious that we know that if we're delivering and we need to have, for example, dystocia drills. We need to have electronic fetal monitoring, which by the way, is available in ECRI. We have an obstetrical suite in there that's offered to all free. It's available 24/7 online that you can take classes. We're about to launch another program in the obstetrical care area. So that's when I think everybody gets that piece, but they don't always get what do you do if you're kind of referring out, and I would say to you that while if you don't provide obstetrical services through FTCA, a deemed provider, and that includes your prenatal, your labor, your delivery, your postpartum care, then they would be exempt from the requirement. But as a nurse, I came to HRSA after 33 years of working in the hospital setting. I was very involved in risk management and have my Masters in Patient Safety/Risk Leadership, and I would challenge everyone to say why would I not want to give my patients the best and most comprehensive care. There's a saying that there are some patients we cannot help, but there are some we cannot harm, and so our challenge would be while you may not be required to have obstetrical service training, I would say you know now as the postpartum period is being extended to almost a year postpartum or am I looking at that patient who comes in the door with maybe an upper respiratory infection, but am I realizing that perhaps this is actually postpartum cardiomyopathy that's showing itself four to five months postpartum. So based on that, we have built courses in ECRI. There's a three-level course we've just released that is ideal for people who maybe aren't doing the obstetrical services per se, but they are taking care of women in that childbearing age or pregnant individuals. I want to make sure that people are aware that those resources are readily available for you. We build them with ECRI, and they are based off of the claims experiences we're seeing from that primary care setting, and I challenge you that we don't want to harm any patient, and that is really the high focus of FTCA.

Leisa Niggel

Thank you, Patty. Can we go back one slide to the final reminder slide? So I'm going to ask as many of the questions in the queue that I can. If you still have questions that aren't answered, I wanted to pull up this slide because the fourth bullet shows where you can pose your questions if we don't get to them today. So the first question in the queue, risk management training: can training go back 12 months from FTCA site visit or only within a calendar year?

Mary Coffey

I was just going to jump in. But thank you, Leisa, and thank you for the question. The FTCA training plan, and we will look at, this is 2022, we'll look at last year's and what you have up to date for this year, and whether it's calendar year or if it's another cycle that you have come up with, you need to be sure that it's clear in your policy and procedure what your year is defined as.

Leisa Niggel

OK. Thank you, Mary. The next question is we have been doing quarterly risk management reports to the board. Will this suffice as long as the content of the reports aligns with the requirements described for annual reports?

Mary Coffey

Yes, it's very helpful to be conducting quarterly assessments, which is the requirement, but also to report to the board, so that you're demonstrating to the board what actions that you're taking to prevent occurrences. So when you do it on a quarterly basis, then you will have a final report or a total of that report for the year, which then you can use as a baseline for the next year moving forward.

Leisa Niggel

Thank you, Mary. The next question is: will this webinar count toward risk management training?

Mary Coffey

I will say yes that it will apply towards risk management training and to keep in mind for the risk managers, whoever is overseeing the risk program, your training needs to be more than just the typical and required training. So this would actually be an excellent one for you to have participated in, if I may say so myself.

Patricia Breen

And Mary, I'll jump on to that as well. While it may help to fulfill that, I would strongly encourage you to continue to look at the risk at your facility and make sure that your trainings are also keeping you up to date in those arenas as well as in the patient safety risk management world as well. It would be hard to narrow down the risk management information you would need in a year to one training.

Leisa Niggel

Thank you, Patty. The next question is: what is the difference between operational site visits and FTCA site visits?

Patricia Breen

Mary, do you want us to take it, or are you good?

Mary Coffey

The operational site visit is conducted every year, I mean, I'm sorry every 18 months, I just probably sent a bunch of people on the floor there for a minute, and you could pick yourself back up. And now it's every 18 months, and it covers all of the components in the Health Center Compliance Manual. The FTCA site visit, and this is a very condensed version just so you know, the FTCA site visit is not routinely done, and the other piece to this is it's a deep dive into the four areas we discussed today. That doesn't mean we won't look at other things, but it's the deep dive into risk management, QI/QA, credentialing and privileging, and claims management.

Leisa Niggel

Thank you, Mary. Is there a site visit checklist?

Mary Coffey

I'm not sure what that means, but if you're wondering if it's a checklist like pre-site visit call completed, there isn't anything like that. You will receive the documents that you requested. You will receive that in a checklist format.

Leisa Niggel

Thank you, Mary. The next question, what manual is the presenter referring to when discussing meeting FTCA criteria?

Mary Coffey

OK, great question. And I'm going to give you three of them. There is the FTCA policy manual, then referenced PAL, that's program assistance letter 2022-01, and that is the deeming requirements for this upcoming cycle, and then, of course, the Health Center Program Compliance manual. Within the Health Center Program Compliance manual Chapter 21 is the FTCA portion, but however, Chapters 5 and Chapter 10, Chapter 5 for clinical staffing and credentialing and privileging and then Chapter 10 for QI/QA also overlap.

Leisa Niggel

OK.

Patricia Breen

And Lisa, if I could point out that we have on the website, which again is available to all health centers, free clinics as well as PCAs, we do have the equity guidance on the FTCA program for the health center providers and staff, and while it is coming out under a contracted version, it gives good guidance on ways that you can meet the requirements for the FTCA program, so I would highly recommend that you explore that resource as well.

Leisa Niggel

Thank you, Patty. The next question: will QI/QA subcommittee meetings also count toward the six meeting minutes required for QI meeting minutes?

Mary Coffey

So that's a great question, and it's one that does come up, and what I would have you do is take a look at your structure. What does your QI structure look like? And you know, typically a structure begins with the Board of Directors and then of course your Executive Director or CEO is then delegated with making sure that the plan that the board has approved is implemented. And then within your plan, it talks about your different committees. So your committees would, depending on the size of your organization, report up to the key leadership and management, and I can tell you that there are so many different varieties of structures in place. So what you want to make sure is that you're providing the minutes that you've discussed in your plan, but the easiest for you would be for your subcommittees to report to an overall quality committee, and then you wouldn't have to report or present two sets of minutes.

Leisa Niggel

Thank you, Mary. The next question: in Illinois, medical assistants are not required to be certified to work at a health center. On that note, what is the credentialing and privileging requirements for medical assistants?

Mary Coffey

Great question in that medical assistants are not required to be certified or registered in in many states, so it's great that you brought this up; however, an unlicensed registered or certified staff is other clinical staff, and they are required to undergo all the same components as your LIPs and OLCPs, except for the licensure certification, registration, and DEAs. But they're still required to have fitness for duty, communicable disease, have some type of a competency checklist or privilege sheet, whatever you call it in your organization, government picture IDs, National Practitioner Data Bank queries and all the rest of that that was listed today.

Leisa Niggel

Thank you, Mary. Next question, where can I find reference to the requirement for peer reviews to be done quarterly?

Mary Coffey

You'll find that in chapter 10 of the Health Center Program Compliance manual.

Leisa Niggel

Thank you. Next question: can the organization choose which privileging and credentialing and files to submit or are the files chosen by the FTCA representative?

Mary Coffey

The files are chosen by the FTCA representative who will submit a staffing list and then the assigned reviewer for credentialing and privileging will highlight those names and return it to you through the Citrix ShareFile, and then you can begin to gather your records.

Leisa Niggel

Thank you. If physician’s assistants require physician oversight by state law, are they an LIP or an OLCP?

Mary Coffey

They are typically an LIP. However, if they are required to have oversight, then they would have a collaborative agreement, and that collaborative agreement should be included with your credentialing and privileging file.

Leisa Niggel

Next question: are files required to include clinician's CEs?

Mary Coffey

We request training, so it depends on how you are going to provide us with the training that the provider has taken, especially when it comes to specialty trainings, things of that nature. So that is up to you if you're not demonstrating training through that list, then you do not typically need to submit it. But if you are chosen for a site visit, I would make sure that you clarify what training is required for those files. And just to follow up with that, many times we try to make it as easy as possible knowing that this is an insurmountable task. We understand that, but we may just ask for your training on the individuals that were chosen for credentialing and privileging.

Leisa Niggel

So we are out of time for questions. Again, if your question was not answered, you can get them answered by contacting Health Center Program Support or the phone number that is currently on your screen. Once again, thank you for participating in the webinar. Please take a few minutes to complete the post-webinar survey. A link to the survey will be provided in a follow-up email after the webinar. We will now end this session. Have a good day.