Elizabeth:

Hello, and good afternoon, or good morning to folks on the West Coast. Welcome to today's webinar, the overview of the CMS Emergency Preparedness Rule. This webinar is sponsored by the National Association of Community Health Centers. My name is Elizabeth Zepko. I'm a Program Associate in the training and technical assistance department here at NACHC, and I'm pleased to bring you this webinar along with my colleague, Susan Sumrell, Deputy Director of Regulatory Affairs, Policy, and Programs. Before we get started, I would like to make a few housekeeping announcements.

Elizabeth:

You have joined this online event by calling in. All lines have been automatically muted. This is to avoid any background noise interference. The duration of this webinar is approximately 90 minutes, including introductions, presentations, and Q&A. If for some reason you do have a question during the webinar, feel free to use the Q&A box located in the right-hand side of your computer screen. Everybody, if you would just take a moment, the only way that we're going to be taking questions throughout today's webinar is using the Q&A box that's located in the lower, right-hand side of your computer screen. Type your question in at any time and please hit send. We will be answering questions periodically throughout the webinar and then at the end of the webinar. Questions will be answered based off of the content.

Elizabeth:

Let us remind you that today's event is being recorded and will be available online on the MyNACHC learning Center within two weeks. At the end of today's webinar, you'll also be presented with a brief survey. This survey lets us know how we did, how valuable this webinar was to you, and directly informs us of future trainings and technical assistance. We value your feedback and encourage you to complete this survey.

Elizabeth:

At this time, I'm going to turn things over to Susan who will be introducing today's speaker. Susan?

Susan:

Thanks so much, Liz, and thank you all for joining us today. Good afternoon, as Liz said, and good morning to you out there on the West Coast. This is a very important webinar, we're glad to offer it to you today, to talk about the new rule on emergency preparedness. We're very lucky to have Molly Evans, who is a partner at Feldesman-Tucker-Leifer-Fidell, join us for today's webinar. As many of you probably know, Feldesman Tucker serves as NACHC counsel, and Molly is definitely no stranger to health centers.

Susan:

She worked with health centers on a variety of issues, including the management of clinical, employment, and workforce related risks, with a focus on issues like Federal Tort Claims Act and HIPAA matters. Today, she's going to give us an overview on the CMS Emergency Preparedness Rule, and what you need to know as a health center.

Susan:

In order to allow as much time as possible for Molly to give her presentation and get through your questions, I'm going to turn it over to Molly.

Molly:

Thank you so much, Susan, and thank you, Liz. I'm delighted to be here this afternoon, here on the East Coast, with you all to discuss this new CMS rule on emergency preparedness and try to troubleshoot some of the concerns that you might be having in terms of coming into compliance with the rule, and give you some, likely, good news about what you've probably already done to be in compliance with this rule that you weren't aware of based on some of the other activities that you're already responsible for participating in as a health center.

Molly:

We're going to review the current requirements on emergency preparedness that you have as health centers. I have the term requirements in quotation marks, and I'll explain that a little more in a minute. Then, we'll talk about this new Emergency Preparedness Rule, which actually extends well beyond health centers, to 17 different provider types, Medicare participating provider types, of which health centers are one.

Molly:

We'll talk about the components of that rule and how it works with you as health centers. Then, try to identify some of the resources that you can use in developing your emergency preparedness plan, some of the training that you're going to be required to do, some of the policies and procedures, and some of the communication plan that is going to be required under this rule.

Molly:

I will say that this rule is new. CMS itself is actually developing guidance that will be published likely at the beginning of the year, they say in January, but in any event, early in the new year, that will tell us a lot more about what the expectations are around the rule. Also, will hopefully give healthcare providers, like health centers, some guidance on documents so you're not reinventing the wheel every time.

Molly:

The current requirements, and for those of you who have attended Feldesman-Tucker trainings, you may be familiar with. This is something that sticks in our craw sometimes, I should say, that HRSA has 330 guidance and PINs and PALs that it uses as term requirements to refer to, but in actuality, PINs and PALs are guidance documents, and policy manuals are guidance documents. While these things are not necessarily requirements, we in the health center world treat them as requirements because we want to get it right. We don't want to run afoul with any HRSA guidance. We want to get 19s out of 19s on our operational site visits.

Molly:

While this emergency preparedness responsibility has shown up for a long while for health centers, in various PINs and PALs, it's new to the CMS rule. As you'll see when we go through it and take a step back and look at these 330 requirements, you'll see that a lot of the information reflected in the new rule is something that you've already seen quite a bit of in your 330 universe.

Molly:

Starting out with PIN 2007-15, which is Health Center Emergency Management Program Expectations. If you think back to that PIN, and I'm not sure to those of you who are new to the health center program, there used to be another PIN called PIN 98-23, which was the Health Center Program Expectations, which really gave a comprehensive look about what HRSA expected health centers to do. That PIN was repealed and replaced with the 19 program requirements, but there was a follow-along PIN called PIN 2007-15 that discussed, specifically, Health Center Emergency Management Requirements.

Molly:

As far as we could tell, and there have been great efforts to try to determine the validity of the PIN, and it's been difficult to tell, but as far as we know, that PIN is still valid. We'll see what happens when the compliance manual is published. At this point, that PIN is still valid, and health centers have had, since 2007, emergency management program expectations. We'll talk about some of those and how they relate to these CMS rules.

Molly:

Additionally, health centers are completing an annual emergency preparedness report with any SAC application that goes in. That's Form 10, and I actually have a screenshot in the slides to refresh your memory if you haven't seen that in a while or you're not the person at the health center that fills out that. Health centers are responding now to the federal government about their emergency preparedness efforts through this SAC application, Form 10. This is another opportunity to bring all of this information and guidance under one umbrella for the health center in terms of how you might manage an emergency preparedness, an emergency response effort at the health center, and how a particular department of the health center will manage that.

Molly:

Finally, we have, also under these 330 requirements, PAL 2014-05, which, when published, really described an updated process for adding sites, temporary sites in emergencies as part of a change in scope. It's an expedited change in scope process that health centers could take advantage of in an emergency.

Molly:

Other ways that emergency preparedness has shown up, we'll talk more specifically about PIN 2007-15. You'll see that PIN 2007-15, and I have a link to it here, says that an emergency management plan, also referred to as an EMP, is essential to minimize the disruption of services for patients, assure the health center's ongoing financial and organizational well-being, and link the health center to the local community response. You'll see that language echoed in these new CMS rules in terms of giving you the confidence that you're doing a lot of the things that this rule is going to require you to do.

Molly:

Also, you should see that in that PIN, since 2007, health centers have been expected to conduct a risk assessment such as a Hazard Vulnerability Analysis, and that the emergency management plan has an all-hazards approach, meaning that the health center really looks at all possible things that could go wrong and have some ability and flexibility to respond to those kinds of emergencies in an all-hazards approach instead of one response.

Molly:

An example of that might be, and actually this is a question that came up to the CMS teachers when they were doing a conference call, this was a community provider saying that they were three miles from a nuclear power plant and that their emergency plan really related to when there's an issue at the power plant and how they might respond to it. Either evacuation for radiation or responding to sick power plant employees. The CMS panelists remarked that really the plan needs to have an all-hazards approach and could not just... For example, in that example, specifically only apply to reacting to a nuclear problem coming from the power plant. Again, this all-hazards approach is important and shows up again in the CMS rules.

Molly:

Finally, you'll see training and testing has been a part of the health center program since this 2007 PIN as well, where you have ongoing training that you conduct with all members of your staff at all levels of the organization around emergency management and implementation, and that you test and evaluate the effectiveness of the plan on an annual basis.

Molly:

Finally, participating in community level risk assessments and integrating that with your own individual risk assessment was another important component of this PIN.

Molly:

What I will say about evaluating compliance with PIN 2007-15 is that, in my experience in helping health centers prepare for operational site visit and looking closely at the site visit guide, there hasn't been a lot of attention from HRSA, to date, on health center emergency preparedness efforts. It hasn't really been a focal point of either the site visit guide or the 19 program requirements or operational site visits in terms of evaluating whether a health center is doing all of the things it needed to do under 2007-15. A question that comes to mind for me is that now that this Medicare rule will be in place, will that be something that HRSA considers important to add as an area of focus in the OSV that they might not before? Obviously, the OSV should relate only to the 330 requirements, but if we have these existing from in 2007-15, it could be something that comes up now that there's more attention to it from the federal level.

Molly:

The other 330 related effort that I was talking about was this Form 10, which I have here. You'll see a lot of the questions that you answer when you complete a SAC application are reminiscent of those in 2007-15. Then, also, in the CMS rule. Has your organization conducted a thorough hazard vulnerability assessment? Does your organization have an approved EPM plan? Does the plan address the four disaster phases, etc.? These kinds of things. This is an opportunity to evaluate what you're telling HRSA anyway. Sometimes we have experiences with clients where the person that completes the grant application is not necessarily the person that actually conducts the boots-on-the-ground emergency efforts, or whatever it is. If it's the FDCA application or deeming application. Making sure that those answers can be supported through documentation is important. Aside from this CMS rule, it's a good opportunity to get all of your ducks in row in terms of the kinds of things that you said you're doing around emergency preparedness and making sure you have support for that.

Molly:

You'll see this is page two of that. Does your organization staff receive training? Are you participating in a coordinated effort or do you have a communications system? Again, if you're sitting there thinking to yourself, why is she going over the 330 requirements? We're here to talk about the CMS rule. I just want to reflect that a lot of the things that you're going to have to do as part of the CMS rule you were already doing, or should already have been doing, as part of your 330 requirements. That should ease some of the anxiety about participating.

Molly:

The other requirements around emergency preparedness really relate to more FTCA related efforts, and in actuality, are more emergency response efforts, rather than emergency preparedness. We don't see a whole lot of overlap between the FTCA related parts of emergency preparedness response and the CMS rule, but nevertheless, it's important to know that the FTCA efforts in terms of responding to emergencies, it's always a good opportunity to remind yourself that there are particular responsibilities that the health center has to take on when it's responding to emergencies in order to assure FTCA coverage for its providers and for the health center, in the event that it's responding to an emergency. This is just a screenshot of the FTCA policy manual that is a reminder of how that works, at least at the beginning of it.

Molly:

Moving on to slide 13. Again, the final 330 requirement being PAL 2014-05, which is that Updated Process for Requesting a Change in Scope. Again, really relates more to emergency response than emergency preparedness. This is just, again, a screenshot of that PAL to the extent you need the reminder that that's how you would go about adding sites, temporary sites in an emergency.

Molly:

Finally, considerations around HIPAA are also important in emergency preparedness and response. Office of civil rights has spoken to these efforts. That has not necessarily been coordinated with the CMS rule around emergency preparedness, but also something to pay attention to in terms of the universe of laws that health centers need to be paying attention to when they participate in emergency preparedness and response activities. Preparedness activities, in terms of joining a healthcare coalition where you might be exchanging health information, just making sure that you have the appropriate protections in place for HIPAA privacy and security issues, is important in terms of that kind of preparedness effort.

Molly:

Some background on the rule. Now we're on to the CMS rule itself. Some background is that CMS really found when evaluating the landscape of emergency preparedness that, while most entities had emergency preparedness requirements, that they didn't go far enough to ensure that they were prepared in the case of an actually emergency. More so, the plan on the shelf rather than an ability to respond in an actual emergency. CMS also found that, while there was a uniform national emergency response that had initially come up after things like 9/11, both state and local governments had cut a lot of their preparedness funding in the years 2010 to 201, which really followed the recession in 2008. Budget tightening, generally. It stands to reason that among the things that are cut are funding around preparedness.

Molly:

In an effort to really ensure that all Medicare provider types, and that's really how CMS found its ability to reach provider types across the country in every sort of community. They did it by using these Medicare conditions of participation as a way to require providers of all kinds to have these emergency preparedness provisions in place. You'll see in the bullet that CMS determined, and this is no surprise to anyone, that maintaining a preparedness program, not just creating it, but having one that is maintained on an ongoing basis, is really a primary means to deal with a large influx of individuals after a disaster. Otherwise, in CMS's mind and in other national experts, putting that plan on a shelf just gets you out of practice to the extent there is a need to respond to an emergency, particularly when there's a large influx of individuals.

Molly:

The proposed rule was originally published in the Federal Register in 2013, so this has been a long time coming. There were a significant number of comments, but in reality, it took not until September 16th of 2016 to publish a final rule, after taking into consideration the comments and determining how the rule might be implemented in a way that would work for providers. While the rule was published in September of 2016, it became effective November 15th, 2016. There's a year grace period until November 15th, 2017, for Medicare providers to come into compliance with the rule. Unlike so many things that health centers have to deal with when you have to come into compliance for things that it almost feels like you are late before you even found out about it, you have a full year, or at this point, 11 months to come into compliance with this rule.

Molly:

CMS's main purpose that they describe in this rule is providing guidance to do the following things, safeguard human resources, maintain business continuity, and protect physical resources. That's their shtick on why they're trying to do this, and why it's important for all provider types, all Medicare provider types.

Molly:

The new rule. Here are the 17 provider types that have to comply with the rule. From my perspective, I would think that health centers are well-positioned to handle this rule in a way that some of these other provider types are not, unless they have Joint Commission accreditation or some other form of accreditation from a national body that CMS recognized to be acceptable. This will be new for some of these provider types. People like long-term care facilities, they're a corresponding accreditation organization. Generally, if you are not accustomed to having a lot of regulation and guidance on you like health centers are, or you're not otherwise accredited by an accrediting body like Joint Commission, this will be new for you. It will be new for some of these provider types.

Molly:

The rule goes through each of these provider types. There's some general themes that apply to all of the provider types. Then there are some things that are required only of some providers and not others. We'll talk about some of those. You can imagine that those are going to be specific to provider types that are residential or have inpatient facilities versus those that are outpatient. Inpatient facilities are going to have a lot more requirements about what they can do for their patients and staff who may be stuck in an inpatient facility more so than someone like a health center, which as an outpatient facility, is not going to have the same requirements for things like generators or food and water requirements, things like that, that hospitals will now have under this rule.

Molly:

The four core areas the rule focuses on, and this relates to all provider types, it's not specific to any of the particular 17, all provider types have these four core areas that they have to comply with, with respect to the rule. That's the risk assessment and emergency planning, policies and procedures, communication planning, and training and testing. As I said in the last slide, CMS has tried to tailor these to address the specific needs of each type of entity that has to respond. Some of the risk assessment and emergency planning activities of a hospital would be quite different from a health center. Likewise with policies and procedures.

Molly:

On the risk assessment and emergency planning, we're back to what we talked about in PIN 2007-15 which is the all-hazards risk assessment. It's important for you as a health center to demonstrate that you have conducted an all-hazard risk assessment to get started on your emergency planning efforts. That will be an important component. That risk assessment and emergency planning should be... you should be able to modify it based on the hazards that are most likely to occur in your area. Some of those may be based on a community assessment that you do or a facility assessment. Some are going to be not specific to locality things, like equipments and power failures, care-related crises, interruptions in communications like cyber-attacks, or interruptions in normal supplies like food and water. Those will generally be universally.

Molly:

However, some hazards, for example, earthquakes, an earthquake response and preparedness effort may be more appropriate in areas of the country that are more prone to earthquakes than in others. Or hurricanes. Those kinds of things, where it's unlikely that a particular hazard will strike in your geographic area. There is some flexibility to allow you to tailor your risk assessment and emergency planning effort to the hazards that are likely to face your health center.

Molly:

For FQHC, and this relates I think to most of the provider types as well, that effort needs to be based on and included in a risk assessment using that all-hazards approach. Again, to the extent that it can be both facility-based, so health center specific, and community-based, that will be important. Likely, because this rule will apply to everyone, all of your other community providers, a community-based risk assessment will hopefully be something that is not too much of a heavy lift. Either it will be in place otherwise or something that the health center can work together with its other providers on to conduct.

Molly:

It needs to include strategies for addressing emergency events, and then address certainly the patient populations that FQHCs might see. For example, the services that you need to provide in an emergency, how you might continue the operations, and how you might include delegations of authority and succession plans to the extent that you have certain requirements in the health center about having the CEO make certain decisions, or the CMO, or whomever it is, to the extent that there need to be particular delegations of authority to allow other people in the health center to be decision-makers in the event of an emergency. Those kinds of things should be addressed in your risk assessment and planning.

Molly:

Also, as part of this, CMS says that you should include a process for how you're going to cooperate and collaborate with other local, regional, tribal, state, or federal emergency preparedness officials' efforts to maintain. At this point because this, again, is a new rule and we haven't seen any guidance that follows it, it's unclear of the level of detail of a process needs to be in place in order to demonstrate compliance with this requirement. I would stay tuned for the guidance documents that CMS promises to publish early in the year for those kinds of things to really have a better understanding of what their expectations are and how you demonstrate things like a process for cooperation and collaboration.

Molly:

Let's move on to slide 24. Additionally, facilities have to... Let me go back quickly. I'm sorry. Let me go back to this slide first, back to the risk assessment and planning. The emergency plan needs to be updated annually. Health centers are accustomed to updating their documents, their policies and procedures, their plans, QI plan, etc. on an ongoing basis or whatever interval HRSA requires, so that should not be a heavy lift for health centers. Nevertheless, it's important to note that that plan, there should be evidence that that plan is updated. Either reviewed and revised or reviewed and, if the health center believes that it's in good shape as it is, then that plan is... there's documentation that that plan was reviewed or revised on an annual basis.

Molly:

Okay, policies and procedures. In terms of policies and procedures, in addition to having the emergency plan that you have, the health center will also need to demonstrate that it has policies and procedures that support the execution of the plan. Again, I don't think this is news to health centers. You're accustomed to putting things like this in place to comply with how you demonstrate all the other things that you're complying with as part of your 19 program requirements or otherwise.

Molly:

The policies need to respond to the risks identified in the risk assessment, so they need to be specific to your emergency plan and not off the shelf from a hospital in the area or otherwise. They need to be specific to your needs. They need to address things like evacuation plans, shelter-in-place, how you might track patients and staff during an emergency. All of the various efforts that the health center will need to take place in order to make its emergency plan sustainable, operational, and useful in the event of an emergency. Again, I think that the policies and procedures piece will be another important piece that we will look to see when we review what CMS publishes early in the year in terms of guidance around what things should look like.

Molly:

Moving on. I've covered this a little bit, but let me just get to these other bullet points. Policies and procedures addressing that safe evacuation plan, including what staff is going to be responsible for as part of a safe evacuation, and what patient needs would be as part of an evacuation. How you might shelter-in-place, and how you're going to create a system of documentation that allows you to preserve confidentiality and maintain your files in the event of an emergency, either that takes you out of your health center building, out of your EMR, what kind of medical documentation you're going to put in place. Hopefully, there, again, will be resources out there that will help you to devise plans on things around how that system of medical documentation will take place and what it will look like.

Molly:

Finally, the use of volunteers in an emergency or other emergency staff strategies. How you might use volunteers during an emergency, what that would look like, and how you're going to integrate that process with other professionals that are available during an emergency.

Molly:

As a side note, I don't know if anyone saw yesterday that the President signed the 21st Century Cares Law inside the bill yesterday, and it looks as though there is an opportunity for health centers to now cover volunteers as part of FTCA. Put a note to yourself on that and stay tuned for information from NACHC and your PCAs about what that will look like, but that will be a huge benefit, not just in emergencies, but generally for health centers to allow volunteers to have the access and ability to be covered by FTCA and participate in care in the health center. That's something that NACHC has been working on for a long time.

Molly:

In my years of doing this, I've watched Congress go back and forth on that bill, or on that provision in different bills, in order to allow health centers to get that access to their volunteers for coverage, and it looks like that is becoming a reality. Stay tuned on that, but know that that's something now to consider for using volunteers for emergencies or otherwise, your ability to have access to FTCA coverage for those volunteers. Again, we'll need to see what that looks like from an operational perspective and how we might handle it, but that is exciting news for sure.

Molly:

Let's go on to slide 26 about the communication plan, the third prong in the four prong approach to emergency preparedness that CMS has devised. That is, again, important to ensure that you have a communication plan that is part of your emergency management and emergency preparedness that allows you to ensure continuity of patient care in the event of a disaster. That communication plan should ensure that patient care is coordinated, not just with the health center itself, but with other local providers, local public health departments, and emergency management agencies.

Molly:

I know, for example, here in Washington, the health centers are part of some pre-organized communication plans with other area providers that could be part of what you put into your communication plan in terms of how you do it. There's no need to reinvent the wheel on a lot of these efforts to the extent that you're already doing some of these things for other reasons. It's really an effort to document what you're doing in a way that you can have it apply to compliance to this rule as well. In my experience in working with health centers, a lot of you are doing these kinds of things anyway. It may be a matter of really taking that umbrella and incorporating all the various things you do as part of communications within the health center itself, and then with other providers, public health department, and other emergency management agencies in your community, and really just getting that on paper.

Molly:

Like the policies and procedures in the plan itself, the communications plan needs to be reviewed and updated on an annual basis as well. The rule actually gets pretty down into the weeds in terms of what the communication plan looks like, including having names and contact information for all staff members, all other entities providing services under arrangement. If you're contracted with a hospital to

provide OB, say, at the health center or another community organization that's providing services at your health center, that entity, having the contact information and names of those people as well, the providers for patients, other FQHCs, and then volunteers that these are specific requirements that CMS has laid out in terms of the rule.

Molly:

Additionally, contact information for federal, state, tribal, regional, and local emergency preparedness staff, other sources of assistance, really as an effort to get the FQHC or the Medicare provider in general in shape so that to the extent there is an emergency, that all of this information is presumably at the health center's fingertips in order to access. Again, these are concepts that I think you've probably seen for a long time to the extent that you've been involved in any emergency preparedness efforts at your local community level or with you PCA or with NACHC. I know that NACHC has issue briefs on emergency plans that date back I think to 2005. We'll talk about resources towards the end of the presentation, but just to be aware that you probably have a lot of this done or done in some form already, so just to be aware of that as you endeavor to come into compliance with this rule by November of next year.

Molly:

Additionally, primary and alternative means for communicating with both the health center staff and then the other emergency management agencies at all the various levels will be important. To the extent that you're typical communications efforts are not feasible because of the nature of the emergency, that there's an alternate means for doing that. A means for providing information about the general condition and location of patients under the facility's care. I think that requirement really relates more to an inpatient type facility. Nevertheless, there is some mention of it in the FQHC portion of this rule. Making sure that there's a means to do that will be important and having that compliance with the privacy rule will also be important.

Molly:

You'll see the site to that privacy rule there which creates a limited acception for talking about general conditions and locations of patients and still having permissibility under HIPAA. Unfortunately, even though it seems like it would be rational, HIPAA generally still applies to health centers and to all healthcare providers in the event of an emergency. There isn't a temporary hold on all of the HIPAA requirements. Making sure that those are also in place as you respond and as you answer questions about patients to family members or otherwise, being cognizant of that limited acception in the privacy rule about general condition and location is important.

Molly:

Finally, acknowledging that you have, as part of your communications plan, a means of providing information about the health center's needs and its ability to provide assistance to the authority having jurisdiction, Incident Command Center, or designee. How the health center is going to communicate with whomever the Incident Command Center of your locality or other jurisdiction is, that means of communication will be an important component of your communication plan that will be required under this CMS rule.

Molly:

On to training and testing. Similar to some of the requirements that you may have as part of the health center's efforts around its 330 requirements on FTCA. Like in FTCA, where every employee should be

trained on medical malpractice in the FTCA. In this case, all employees must be trained on, and I love how CMS says, every aspect of the emergency preparedness plan, and that the training program needs to be reviewed and updated annually.

Molly:

What does that look like? It could be something that is part of your learning management system and some of the required training that you assign to your staff members. I think it can be scalable based on the person's job function at the health center. At this point, again, unless we see guidance that has more specifics around what that training needs to look like, at this point, it seems as though the training can be what the health center thinks it needs to be to the extent that it does cover all the aspects of the plan.

Molly:

That can be scalable, and a patient registration clerk may not have the same need for training around emergency response that the CMO needs. Making those trainings scalable is important, but demonstrating that all employees are trained on the plan will be important as well. To the extent you can leverage your learning management system to the extent that you have one, or if you don't, sign-in sheets and agendas and those kinds of things kept in a way to demonstrate that you're training your employees on your plan will be important.

Molly:

That again, just like policies and procedures in the plan itself need to be reviewed and updated annually. Again, that will be something that surveyors could come in and test you on to the extent that you can demonstrate training of employees.

Molly:

Finally, around testing... Let me actually say a little more on the training, just on the documentation of the training again. I think I got ahead of myself on the last slide. Making sure that you can demonstrate staff knowledge of emergency preparedness through the documentation of that training to the extent that that's a small quiz at the end or however you otherwise demonstrate that your staff has knowledge of whatever you're training them on. Incorporating that for emergency preparedness will also be important.

Molly:

The other piece that would be important to note here is that this rule also says that you have to provide that initial training to all new and existing staff, and individuals providing services under arrangement, and volunteers, consistent with their expected roles. Making sure that you can demonstrate that you're doing that initial training with everyone and then you're doing it again annually. You're updating it annually and you're providing it annually and maintaining that documentation is going to be important.

Molly:

Last but not least, and certainly probably the most time consuming in the end, and maybe least familiar to health centers, at least at this point, is the requirements to meet testing efforts on an annual basis. What CMS has said that the FQHC requirements around testing are include participation in a full-scale exercise that is community-based. If you can't find a community-based exercise, either no one else in

your community seems to be getting on board or coming into compliance with this rule, and/or you just can't find a way to participate in a full-scale exercise with the other healthcare providers in your community, it could be individually-based at your health center.

Molly:

Participating in that full-scale exercise on an annual basis is a testing requirement under this SQHC rule. The only exception to that is that to the extent you actually had to activate your emergency plan, and in any given year, you would be exempt from the testing for one year. You get a small reprieve from that testing to the extent that you have to activate your plan, which is in it of itself, going to be not much of a reprieve. Nevertheless, that participation in the full-scale exercise that is documented is going to be important.

Molly:

Then, a second exercise that the health center conducts, either another full-scale exercise or a tabletop exercise that includes a meaningful group discussion led by a facilitator is going to be an important component of demonstrating compliance with the testing requirements that CMS has established as part of this,

Molly:

Again, because all of the other provider types, of the 16 other provider types in your community, are going to have to comply with this rule. Hopefully, there's some economies of a scale available in terms of how you might participate in a community-based exercise that allows the health center to do so in a way that is not overly burdensome, but useful and gives you that ability to meet that expectation that you're doing that on an annual basis.

Molly:

As part of these efforts on testing, not only do you do the testing that is required under the CMS rule, it's also necessary to analyze the health center's response and to maintain, again, documentation of all the drills, tabletop exercises, and emergency events that you do. Then, to the extent that your testing demonstrates that you need to modify, improve, or whatever, your emergency plan, that you do so. That your revisions to your emergency plan are advised by what you learned when you conducted your testing. Again, that will be part of the documentation that you could have a Medicare surveyor come in and review regarding your compliance with that aspect of the rule.

Molly:

To the extent that the health center is part of an integrated healthcare system. The way that CMS explains it says, if the health center is part of a healthcare system consisting of multiple separately certified healthcare facilities, it can elect to have a unified and integrated emergency preparedness program and participate in the coordinated emergency preparedness program. That provision, to me, was a little confusing in terms of who we're talking about when we talk about a unified and integrated emergency preparedness program. They're really talking about, in that case, to the extent that you have a large healthcare system that has within it a hospital, long-term care facility, hospice program, etc. They're not talking about different entities that are not under the same corporate umbrella participating in the integrated healthcare system, at least for this purpose.

Molly:

There are plenty of opportunities for community involvement and integration, but when they talk about a unified and integrated emergency preparedness response with respect to an integrated healthcare system, that's generally what they're referring to. That is clarification that we got from CMS directly after asking some questions on what they intended to mean by that. If, for some reason, the health center is part of an integrated program and it elects to have that unified program, it must demonstrate that each separately certified facility has actively participated in the program. There's not an ability to coast on someone else's efforts and be along for the ride. The program, each has to demonstrate compliance with it. I'm not really sure that it's that helpful anyway to those organizations that are part of an integrated system.

Molly:

Moving on to slide 33. More information around those uniform program requirements. Again, these really go to say that each facility has to have a meaningful participation in that unified program. It can't just be that the mega-hospital runs the show and the other smaller facilities don't really have a lot of input or responsibility in taking care of that effort.

Molly:

Also, within that uniform program and uniform and integrated response, it needs to include a documented individual facility-based risk assessment for each separately certified facility as well as that community-based assessment. Again, the requirements are not reduced in any meaningful way for participation in the uniform response.

Molly:

Resources. These are important, more so than you might find in other efforts that the government has put out because of the many, many types of healthcare facilities that have to respond and come into compliance with this rule. It does seem, from my review of the efforts, that CMS is making a meaningful response and trying to get documentation out there that really is helpful. Make sure that you look at that first two bullets in red on emergency preparedness requirements for Medicare and Medicaid participating providers.

Molly:

There is a full Topic Collection on ambulatory care and federally qualified health centers. If you look on there, you might recognize a lot of the documents that are in there. They have a library of documents that CMS considers to be useful to ambulatory care and federally qualified health centers. They include things like some of the NACHC issue briefs. I saw a healthcare emergency preparedness effort that CHCANYS had done. A lot of PCA or NACHC documents you'll find in there which may help you develop your emergency plan or improve it or help with policies and procedures and those kinds of things. I imagine that CMS will continue to update those to provide facilities with the ability to have as much guidance as possible as they try to come into compliance.

Molly:

Then you'll see, there are some FEMA links here that might be helpful. Some of them may be overwhelming and too much to try to take on as you write either your risk assessment or your emergency plan, but, again, something to take a look at and consider as you do that.

Molly:

Finally, my contact information to the extent that you have follow-up questions for things that I didn't answer, or I didn't answer clearly enough, or I didn't address clearly enough. I will say that this, again, is a work in progress because it's new to everyone and because we haven't seen the guidance coming out. I think that there are a lot of questions that might still be up in the air, but to the extent that I can answer them or I can follow up directly with CMS to answer them, I'm happy to do so.

Molly:

Before I take some questions, I did want to just note what I found to be interesting in the rule itself where CMS has actually referred to that PIN 2007-15 to say that, by the way, health centers should be able to comply with this pretty easily because we know that they already have to do that. In the rule, CMS came up with what they call burden hours and dollars, how much it's going to cost particular providers to come into compliance with this rule.

Molly:

CMS has said that it shouldn't take that much time or money for health centers to do it because they're already doing it as part of their requirements to comply with the emergency management program expectations. It says, a review of the emergency management PIN indicates that some of its expectations are very similar to the requirements in the final rule. While the expectation set forth by HRSA and the emergency management PIN are not requirements for receiving the health center program grants, it first defines that if FQHC is not meeting the expectations of the emergency management PIN, it would provide the FQHC with resources for technical assistance to assist them in meeting these expectations.

Molly:

My experience is that HRSA is not providing technical assistance on emergency management to health centers, but maybe they will be now. The rule also says, furthermore, in accordance with the emergency management PIN, FQHC should have initiated their emergency management planning by conducting a risk assessment such as a hazard vulnerability analysis. That hazard vulnerability analysis should identify potential emergencies or risks or potential and indirect effects of the facility's operations and demands on their services, and prioritize risks based on the likelihood of each risk occurring and the impact or severity that the facility will experience if the risk occurs. FQHCs are also encouraged to participate in community level risk assessments and integrate their own risk assessment with the local community.

Molly:

Despite these expectations and existing Medicare regulations for rural health clinics and FQHCs, some risk assessments may not comply with all the requirements. For example, FQHCs do not specifically address our requirement to address likely medical or non-medical emergencies. In addition, participation in a community-based risk assessment is only encouraged and not required.

Molly:

The bottom line being that they say that we expect that all 4200 rural health clinics and 6500 FQHCs will need to compare their current risk assessments with our requirements and accomplish these task necessary to ensure their risk assessments comply with our requirements. However, we expect that FQHCs will not be subject to as many burden hours as rural health clinics. Even CMS believes that health centers are ahead of the game in terms of how you're going to respond to this. If you are interested, if me reading that wasn't enough for you and you're interested in that, I'm happy to provide the page

numbers in the rule to let you read further CMS's thinking, specifically on how health centers are going to comply with it, comply with the rule. The rule is 649 pages. This discussion regarding FQHCs starts on page 475, but I'm happy to point anyone into that direction if you feel that would be helpful or interesting in any way.

Molly:

I only, so far, see a couple of questions which we can look at now. One of which is, what is the purpose of shelter-in-place? In terms of how the health center identifies to certain, I'm sorry, addresses certain risks or emergencies, shelter-in-place being one of those that may be appropriate for the health center to utilize in the event of a certain emergency. I think that CMS's purpose is to make sure that is a consideration. That's a general emergency management and response technique. To the extent that that's appropriate for a health center in a particular emergency, at least that's my perspective of what they're doing, what they're asking you to do.

Molly:

I will say, though, that while CMS may ask health centers to consider various efforts as part of both making their plans, making their policies and procedures, their communication plan, and their training and testing, it certainly up to the health center to determine what they feel is appropriate or not based on the health center's geographic location, attachment to other community providers, or otherwise. Maybe shelter-in-place doesn't make sense for particular health centers. I think that's an example of a technique that CMS would like provider types to cover or at least explore in developing their plan.

Molly:

Then, another question I see here is, can you recommend a consultant or consulting group to help us design our plans? I cannot at this moment. NACHC may be able to have some resources around that. I know that a couple of the PCAs like MassLeague and CHCANYS have well-developed emergency preparedness departments. They may be able to help you refer you to a consultant. I would, again, start with the NACHC issue brief that you can find on the NACHC website. You can also find it on the CMS website. You'll see here on this first bullet, this asprtracie, if you look in that Topic Collection for federally qualified health centers you can find it there as well and see what you might be able to do to start out before you have to start exploring using consultants to do it.

Molly:

I'm sure that this will bring out a lot of documents and a lot of efforts by various groups and associations. If you think about all of the 17 provider types having an association similar to NACHC, I think that there will be a lot of work that comes out of this that will be made available to health centers to help develop their plans. I would stay tuned to what NACHC and some of the other PCAs are going to be doing to help you as well.

Molly:

I don't see any other questions, at least in my Q&A box. I don't know, Susan, if you see some that I don't, but I'm happy to answer any questions. We have about 25 minutes left to... Here we go. Here's some more. Go ahead.

Elizabeth:

Actually, before we. I'm sorry. I know Susan is going to run the Q&A box. I'm going to let Susan go ahead and read them off. Folks, if you have any questions for Molly, this is definitely the time to go ahead and reach out. Get this on recording so we can listen to this on the playback afterwards. I'm sure a lot of your colleagues may have the same exact question. You can place your questions into the Q&A box. It's located in the lower right-hand side of your computer screen. You might have to open the tab right there. All you need to do is just type in your questions and hit send, and we will answer questions pretty much in order based off what we have. So, Susan, I'm going to let you take it away.

Susan:

Sure. I've seen a couple of the questions come in and they're similar variations on the same theme. I want to start with the question, can you talk a little bit more about the definition of facility? A lot of people asked, does this apply organization wide or do I need to have a plan in place for each site? What do you think about that, Molly?

Molly:

That is a great question. I'm actually going to try to look at the rule while we're talking to make sure that we get the answer correct. I think that if a health center has various sites, that each have their own Medicare certification, then you may be considered to be as part of one of these integrated systems where you could have an approach that the health center itself, with its various sites, has a, quote, community-based drill that would be satisfactory. The health center would have an emergency plan. The health center would have a drill. The health center would have policies, but each of the sites, to the extent that they have differences, would be acknowledged and recognized in the plan. Each of the site's staff members would be trained, etc. Things like that.

Molly:

If I can look to the rule while we're answering questions, too, I can confirm that, but I think that's... At least, that's my impression of how CMS is interpreting that. I get that also because they say that there are 6000 FQHCs, which to me means they're referring to separately certified sites. In that case, I think we would be talking, perhaps, we would try to use the integrated rules that we covered at the end of the webinar to address that concern, so that each site isn't starting from scratch with its own plan.

Susan:

Certainly, and this is Susan. Just a tidbit. CMS requires, generally, and I think this is what you're saying, Molly, but generally, CMS sees each site as its own FQHC. They don't see the whole organizations like HRSA does. You mentioned Medicare certification, and I never take an opportunity to miss reminding folks that it is important that you have a Medicare certification for each of your individual sites.

Molly:

Yes, I echo that strongly.

Susan:

The lawyers tend to agree with me when I say that. The next question is, how do you think this will apply if there's a health center that has a couple stand-alone dental sites? Do they need to have a plan in place? A variation on that last question.

Molly:

I think it depends if they have a Medicare certification for that site. That's really going to be the test that would trigger your requirement to comply with the rule.

Susan:

Great. Thank you. The next question is more on the facility-based exercises. What are the timeframes of those exercises, and do you have any examples of those exercises? That might be something that might be coming in the additional information.

Molly:

I think so. The timeframe meaning, should the exercise take all day or could it take a couple hours? The exercises need to be performed every year, if that's the question. Annual requirements. I think that some examples will be coming. Some examples are in the asprtracie website. That's a training website and I believe they have some sample exercises there. They had an active shooter drill, I believe. I also believe that, again, some of the PCAs have exercises that you might be able to take advantage of. I imagine that as this becomes more real for everyone, it will be something that we see more of in terms of NACHC responding to health center needs around this as well.

Susan:

Great. Thank you. Another question. Does shelter-in-place contradict NFPA 101?

Molly:

I'm not sure what NFPA 101 is.

Susan:

Okay, let see if we can more information on that one. The other question is a good one, and I think you addressed it at the beginning. What is the deadline for FQHCs to have this in place?

Molly:

November 15th, 2017.

Susan:

Great. It's a good time to start and to think about this right now and to get started.

Molly:

To me, it feels refreshing to have 11 months to do something. I feel like we're always trying to scramble because things come out quickly and then you're already late on them. It seems like there's ample time, at least, to ramp-up. Not to understate how much of an effort it will be for health centers to handle this, but there is some ramp-up time.

Susan:

Sure. We did get some help, thank you, Tina, for this, NFPA is the National Fire Protection Agency. Is that one that you want to look into, Molly, about shelter-in-place and possibly contradicting that?

Molly:

Yes. I'm trying to, again, I've pulled the rule up here. In terms of what they're talking about when they're talking about shelter-in-place... Here's a comment that CMS addressed regarding shelter-in-place. It says, the commenter stated that we should delete the requirement that we proposed that 482.15 before, that a hospital must have policies and procedures to address the means to shelter-in-place for patients, staff, and volunteers who remain in the facility. The commenter inquired about what they should do with patients that decide they are not going to be sheltered-in-place and rescue crews cannot make it to the hospital to remove them. Plans should be made to shelter all patients in the event that an evacuation cannot be executed. We stated in the rule that the provision should be made for patients and staff whether they evacuate or shelter-in-place.

Molly:

At this point, we'll see. I'm having a look at that further, but it's definitely clear that CMS has an expectation that there are provisions for sheltering-in-place depending on what the emergency is. We'll go from there.

Susan:

Great. Thank you for that, definitely. Those were the questions. I was just scanning through to make sure we've... I think we've answered the ones that came in thus far. We did have one that came in that I answered via chat. They had a question about, what bill was the FTCA for volunteers included in? For those of you that are curious, it is called the 21st Century Cares Act. It was just signed into law, as Molly mentioned, yesterday by the President. If you Google 21st Century Cares, there's an entire webpage dedicated to it and all that is in it. It's a massive bill, but we were very excited to see that included in there. It's like you mentioned, a very long time coming.

Molly:

Yes, the only thing I would say that I want to take a closer look at is it seems to imply that all you need to do to cover volunteers is have something on your website that says that you're a deemed facility, which, as a lot of health centers may recall, was something that Jim McCray had put out in 2011, saying that all health centers should have on their website a statement that they're a deemed facility and covered by FTCA. From the language in the bill, it seems like that's the only requirement to cover volunteers, but we want to make sure that we have all of our I's dotted and T's crossed on that before we start relying on it for volunteers in order to... Just because it can be goofy otherwise. I would say, stay tuned for more information from NACHC on that.

Susan:

Exactly. If you receive our weekly Washington Update, you hopefully saw that news in that update, but we also have a longer blog post that talks about 21st Century Cares. There was another provision related to ACO Beneficiary Assignment, if that's something you're interested in, in the 21st Century Cares Act as well. Take a look at the NACHC website, on our blog called Health Centers on the Hill that talks a little bit more about that.

Molly:

I did see one question that came in, at least, I see it now that says, does CMS really mean a full-scale, full-scale is defined by Homeland Security, exercise and evaluation program? I actually pulled up the

answer while we were talking. It says that a few commenters recommended that we specifically require that the training and testing program be developed consistent with the principles of the Homeland Security exercise and evaluation program. One commenter believed that our proposed requirement is not specific enough and should lay out exactly what our expectations are for a successful training program and what is exactly required.

Molly:

CMS says, we appreciate these recommendations. The requirements we established are the minimum health and safety standards that facilities must meet. However, the provider or supplier may choose to set a higher standard for its facility. In the proposal, we provided facilities with resources and examples to help them begin developing a training and testing program. We do not believe that we should limit the principles or guidelines that a facility may want to utilize when developing its program.

Molly:

The answer is, no, it does not mean that you need to comply with the principles of HSEEP, or the Homeland Security Exercise and Evaluation Program, but it's certainly a good guidepost to the extent you want to.

Molly:

Then, I think I see one other question which is, how does FTCA coverage work with interpreters or other non-provider health center staff? Well, FCTA coverage covers all employees of the health center and some qualified contractors, so it would cover interpreters and other non-provider health staff. You're covered.

Molly:

The question that I always have for health centers is, what is an interpreter or a non-provider health staff going to do that's medical, surgical, dental, or related functions, or in other words, the things that are covered by FTCA? That question is usually harder to answer, but to the extent that an interpreter or a non-provider health center staff member is named in a malpractice lawsuit, FTCA would cover them just as much as they would cover the provider staff.

Susan:

Thank you, Molly. That looks like everything. I guess I can do one last call for any questions. Please take a minute to enter them into the Q&A box if you have any. If not, I'm going to give you a big thank you, Molly. I think this was a very helpful webinar just to run through and provide some resources, and really give some reassurance to folks that some of this stuff we're probably already doing, given our health center requirements. I really appreciate your time, and I want folks to stay tuned, it sounds like, because we will continue to learn more as additional guidance comes out on this.

Molly:

Absolutely. Thank you, and to the extent that we missed your question, please feel free to email me.

Susan:

Thank you guys. This is one quick plug. I hope you're going to jump off this webinar and then jump onto our next webinar that starts at 3:30 on advocacy work. Through the year ahead, we're going to be

talking about all of the potential changes we might be seeing and two of our big advocacy pushes. If you sign up for that webinar, you can jump off this one and jump right onto that one. Thank you guys.

Molly:

Great, thank you.

Susan:

Liz, is there anything we need to do to sign off and wrap up?

Elizabeth:

Nope, I'll close it down. Thanks everybody. Have a great afternoon. Bye.

Molly:

Thank you. Bye-bye.

Susan:

Bye-bye.