Emergency Preparedness

Ronisha Blackstone, CMS

Ronisha Blackstone: So, good afternoon everyone. Again, my name is Ronisha Blackstone, and I work in the Clinical Standards Group within the Centers for Clinical Standards and Quality here within CMS, and I am going to be presenting for all today on the Emergency Preparedness Final Rule that we released last fall, fall of last year.

I, first, want to thank you all for joining me today, and I hope that you find this presentation informative. We are pleased to have finalized these regulations, which we believe will ensure that providers are adequately prepared to meet the needs of patients during a disaster, as well as establish a more coordinated response.

So, to begin, I really just wanted to survey the room and get a feel from the audience about who in the audience is actually familiar with the CMS Emergency Preparedness Final Rule. So, our first polling question is, on a scale from one to ten, one being the lowest and ten the highest, how prepared is your PACE organization to meet the new CMS Emergency Preparedness Requirements?

Okay, we've got more coming in. Okay, so it seems like its pretty split between a little not prepared and pretty well prepared. So, for those who do feel prepared, I hope that this presentation, hopefully, supports your current efforts in trying to reach compliance, and for those who feel less

prepared, hopefully this presentation will provide you with some information to move you closer to becoming in compliance.

So, the two main objectives for this presentation this afternoon are to provide you all with a general overview of the regulation, in hopes of gaining a better understanding of the requirements in the final rule, as well as provide you all with resources and technical assistance services that are available for assisting you with the development of your Emergency Preparedness Programs.

So, again, I work in the Clinical Standards Group, and our primary responsibility in the agency is to establish, maintain, and revise, as necessary, the health and safety standards that healthcare -- Medicare and Medicaid participating healthcare providers must meet in order to participate in the Medicare Program. And so, the health and safety requirements are known as conditions as participations, conditions for coverage, and requirements for participation depending on the provider type, and they are established in accordance with statutory authority.

The COPs help CMS ensure that providers participating in the Medicare Program provide high-quality care and work towards continued quality improvement, and then in addition, I note that the health and safety standards serve to protect all individuals who receive services from a provider and not just Medicare beneficiaries. And then, the specific health and safety standards related to PACE organizations can be found in Part 460, subparts (e) through (h) of the Code of Federal Regulations.

So, we publish an Emergency Preparedness Proposed Rule in December of 2013, and subsequently finalized the regulation in September of 2016. And, so, the regulation establishes national emergency preparedness requirements for 17 different Medicare and Medicaid participating provider types, including PACE organizations, to plan adequately for both natural and manmade disasters and coordinate with various emergency preparedness systems. So, specifically, this regulation expanded upon

and replaced the preexisting emergency preparedness requirements for PACE organizations found at 460.72, Paragraph C.

And the implementation deadline for the final rule is November 15th, 2017. There is a typo on the slide that says it's the 16th. The correct date is the 15th. And so, by way of background, we began developing the emergency preparedness proposed rule in the wake of Hurricane Katrina when there was a clear need, and, what we believe, a demand for this type of regulation, as evidenced by numerous GAO and OIG reports that analyze provider response in response to an emergency event or disaster, as well as various inquiries that we would receive here at CMS following a disaster.

And, so, our preliminary research included previewing our existing Medicare regulations across provider types, and we determined that they were inconsistent. So, in some instance, you had providers who had somewhat of substantive emergency preparedness requirements, whereas other participating providers had none. And then, in fact, PACE organizations are one of the few providers who did have a somewhat substantive set of preexisting emergency preparedness requirements, including requirements to implement procedures for both medical and non-medical emergencies, of requirement to provide training to staff and participants, as well as requirements to test their disaster and emergency plans annually.

And, so, based on this analysis, we believe there was a need to address the inconsistency across providers in the level of emergency preparedness, and we felt that the existing regulations were not sufficient enough to address communication and coordination, contingency planning, as well as training of personnel. And so, from there, we looked at existing emergency preparedness standards to determine best practices, and we had several goals in mind that we sought to achieve through the regulation.

So, our first goal in developing this regulation was to address the systematic gaps that were identified in the GAO and OIG reports that analyzed provider response after a disaster, and then second, we strive to establish consistency and work to develop a regulatory framework with core elements that can be utilized across provider types, while also tailoring the requirements to the individual provider types' specific needs and their individual circumstances.

And then, finally, we wanted to encourage coordination within communities and states, as well as across state lines. And we believe that emergency preparedness is at its greatest when providers think in terms broader than their own facility and encourage participation in healthcare coalitions.

So, the publication of the proposed rule in December of 2013 did include a public comment period, which we did extend the timeframe for, given the scope and complexity of the regulation, and in response, we received nearly 400 public comments. Commenters included individuals, healthcare professionals, and corporations, national associations, health departments, and emergency management agencies, as well as comments from the many individual facilities that are directly impacted by this regulation.

Generally, commenters were supportive of the intent behind the regulation. We did receive a few comments from PACE organizations and associations who were generally in support of the rule, and, in particular, the need to address communication and coordination with other systems of care. Many commenters noted that, while necessary, the changes would be costly and burdensome for many facilities. And, then, given the complexity of the regulation, many commenters requested that we delay implementation of the requirements for several years, citing concerns of administrative burdens, lack of funding, and then also, the variation of experience among the different providers that are impacted by the regulation.

However, we did receive a few comments in regard to concerns with continuing to delay an implementation or compliance date for these requirements. And so ultimately, in response, we did delay the implementation date for one year, following the effective date of the regulation, to allow providers more time to come into compliance with the new requirements.

And then lastly, a few commenters shared concerns regarding overlap with existing emergency standards, and they were concerned about how our regulations would overlap with them or, in some ways, possibly conflict with such standards. And, so, the final rule does respond to all of the comments that we received, and I do encourage you all to take an opportunity to read both the proposed and final rules if you have not had an opportunity yet.

So, now I will begin to walk through the requirements of the final rule. Again, the implementation date for the regulation is November 15th, 2017, so the date is sneaking up on us. The regulation identifies four elements essential to an effective preparedness program. Each element of the program must be reviewed and updated, as necessary, annually, I will briefly mention them here, and then I will discuss them in more detail as we continue through the presentation.

So, the first element is risk assessment and planning. Under this requirement, all providers must develop an emergency plan using an all-hazards approach and identify in advance essential functions and who is responsible in a crisis. Second, facilities must develop policies and procedures that are based on the emergency plan and the risk assessment, and speak to issues such as medical documentation and evacuation or sheltering in place. Third, there's a requirement for a communication plan that allows for alternate means of communication, providing information to local authorities and sharing medical documentation. And then lastly, the emergency program must contain a training and testing element. I'd note that the specific requirements of

each of these elements are modified based on the characteristics of each provider type required to comply with the requirements of final rule.

Now, the first element requires providers to develop an emergency plan based on a risk assessment. The risk assessment must be documented and use an all-hazards approach. The term "risk assessment" describes a process facilities' use to assess and document potential hazards that are likely to impact their geographical region, in their community, their facility and population, and identify gaps and challenges that should be considered and addressed in developing the Emergency Preparedness Program. We do understand that the healthcare industry may also refer to a risk assessment as a hazard, vulnerability assessment, or analysis.

The plan must include strategies to address events identified in the risk assessment, plans for evacuating or sheltering in place, and arrangement for working with other providers in the area. The plan must also address continuity of operation. So, for example, by addressing operations, we would expect a facility to address the number of individuals they serve, the level of care and services that they provide, and the availability of staff and supplies. And then, lastly, the plan must include a process for cooperation and collaboration with emergency preparedness officials to promote an integrated response.

So, one common question that we hear from providers is, what do we mean by all hazards? An all-hazards approach is an integrated approach to emergency preparedness planning that doesn't specifically address every possible threat but ensures providers have the capacity to address a broad range of related emergencies. So, these may include care-related emergencies, equipment and power failures, interruptions in communications, including cyberattacks, loss of a portion or all of a facility, and interruptions in the normal supply of essentials such as food and water.

We would expect providers to consider their geographic location, business functions that should continue in the event of an emergency,

risks that the provider is likely to confront, contingencies, and also to determine whether arrangements with other providers is necessary to ensure continuity of care.

Each provider is required to develop policies and procedures based on the risk assessment and the emergency plan, and must address a number of topics, including the provision of subsistence needs, alternate energy sources, sewage and waste disposal, and procedures for evacuating or sheltering in place.

So, with regard to subsistence needs, PACE organizations are required to provide for adequate subsistence for all participants and staff for the duration of an emergency, or until all its occupants have been evacuated and its operations ceased. Facilities have the flexibility in identifying their individual subsistence needs that would be required during an emergency, and there are no set requirements or standards for the amount of provisions to be provided in a facility. And then last, I'd note the policies and procedures must also address a system to preserve medical documentation that ensures confidentiality in compliance with HIPPA regulations.

The next element we will discuss is the communication plan. This requires facilities to develop a plan that complies with both federal and state laws. The communication plan must include the names and contact information for staff, participants' physician, entities providing services under arrangement, as well as state and local EP officials. It must include primary and alternate means of communicating with staff and emergency preparedness officials, such as cell phones or satellite systems. And then lastly, there must be a method to share medical documentation and participant information under an organization's care, including their general conditions, as well as their location.

The goal of the communication plan requirement is to ensure that care is coordinated within a provider facility, across healthcare providers, and

with state and local public health departments and emergency management agencies.

And so, the fourth and final element requires providers to develop and maintain a training and testing program. So, after the risk assessment is conducted, the emergency plan is developed, the policies and procedures are in place and the communication plan has been considered, there must be training and testing provided and in place so that all personnel within a facility know how to respond to emergencies that were identified in the organization's risk assessment. So, this element is intended to not only assess the feasibility of a provider's emergency plan through the training and testing, but also to encourage providers to become engaged in their community and to promote a more coordinated response within the facility.

So, specifically, providers are required to conduct two testing exercises annually; one community-based full-scale testing exercise, and then one additional exercise of their choice. And this was a change from our initial proposal that we put forward in the proposed rule, in hopes of increasing flexibility for providers. By allowing providers to choose their testing exercise, we hope this affords flexibility to determine which exercise is most beneficial as you consider your individual and specific needs.

Now, there are a couple of layers to the requirement for the full-scale exercise. As the term "full-scale exercise" may vary by location or provider type, I want to take the time to clarify that CMS considers a full-scale exercise as any operations-based exercise that assesses a facility's functional capabilities by simulating a response to an emergency that would impact the facility's operations in their given community. And, so, we did not define community to afford the flexibility to develop exercises that are realistic and reflect the risk and composition of an individual provider's community. So, however, the term could mean entities within a state or multi-state region.

And, so, we do understand that participation in a community-based full-scale exercise may not be feasible for certain providers or facilities, or this type of exercise may not be readily accessible given someone's geographical location or if you're located in a rural area. So, the requirement does provide the flexibility to conduct a testing exercise that is based on the individual facility. So, this individual facility-based exercise must be sufficient enough to maintain knowledge, knowledge and skills, and adequately test the emergency plan. Lastly, I'd note that in the event that a provider were to experience an actual emergency event that would activate their emergency plan, that facility would be exempt from the testing requirements for one year following the onset of the emergency event. And then, just as reminder, all of these four elements are required to be reviewed and updated as necessary annually.

Now, I mentioned earlier that, in general, the requirements are consistent across provider types, but there are some variations based on the specific characteristics of the individual provider. So, one variation for PACE organizations is that they are required to inform state and local emergency preparedness officials of the need for assistance with evacuations. So, these policies and procedures must address when and how this information is communicated to emergency officials, and then also include the clinical care that is needed for participants.

So, for instance, in the event that a participant would require evacuation, the responsible agency should provide emergency officials with the appropriate information to facilitate the participant's evacuation or transportation. So, this may include whether or not the individual is mobile, what type of life-saving equipment does the individual require, or whether or not this equipment is able to be transported.

And, then, another variation for PACE organizations is the requirement for tracking on-duty staff and shelter participants, both during and after an emergency. So, given that PACE organizations provide a continuum of care for their participants, we anticipate that participants will return for

care following an emergency. So, tracking before and after an emergency allows for a continuation of regularly scheduled services.

We do not specify a type of tracking system that must be used; rather, a provider has the flexibility to determine how to track, whether it uses an electronic database, hard copy documentation, or some other method. I do believe that a number of states already have such tracking systems in place or are under development, and the systems are available for use by healthcare providers, so I'd encourage you all to leverage the support available through local and national healthcare organizations for resources and tools for tracking participants.

So, I mentioned this important date a few times throughout the presentation, and so the second polling question is, what is the implementation date for these emergency preparedness requirements?

Okay. So, it looks like most of you guys are hanging in there with me. The implementation date is November 15th, 2017. Providers were given one year to come into compliance with these requirements, and then enforcement practices for PACE organizations are the same as the current enforcement practices in place right now.

Okay, so with the implementation deadline approaching, CMS has released interpretive guidelines to assist with the implementation of the requirements. In addition, our survey and certification group here at CMS developed a dedicated website to assist providers with meeting these emergency preparedness requirements. This website includes FAQs, sample plans, and other useful information. CMS will continue updating this website as information continues to become available. And then questions about these requirements or enforcement can be submitted to the e-mail address that is on the slide, and then, in addition, we would welcome any information or assistance that you all may have that you feel might be useful to share with others as well. So, we definitely want to hear from you if you have something to share.

And, so, in addition, the Office of the Assistant Secretary for Preparedness and Response, widely known as ASPR, another agency within the Department of Health and Human Services, has been instrumental in providing resources, templates, and technical assistance to the provider community through their information exchange known as TRACIE. TRACIE is a healthcare emergency preparedness information gateway that provides access to information and resources to improve preparedness.

CMS has partnered with ASPR to provide this technical assistance and share resources and best practices to help providers start, continue, or update their documents required by this final rule. TRACIE includes a resource library and topic collections, highlighting specific health and medical preparedness topics, as well as a technical resource domain that provides help with conducting risk assessments, developing the four elements of the requirements in this regulation, and conducting corrective action planning as well. So, we strongly encourage providers to utilize TRACIE as a resource for coming into compliance with this final rule.

And, so, to wrap up, the next few slides contain links to additional resources and important information, including links to both the proposed and final rules, a link to the survey and certification emergency preparedness website that I mentioned earlier, as well as a link to the interpretive guidelines for the final rule where you can find a lot of helpful information in your efforts to come into compliance with the requirements.

And then this slide provides links to the presentation slides, audio recording, and transcript for two additional national provider calls that we held on the Emergency Preparedness Final rule. There likely could be information in these calls that I didn't have an opportunity to discuss here, so I would recommend you guys also checking out the information in these presentations as well.

And then, finally, this slide includes a link to a helpful ASPR document that is supposed to provide various resources at your fingerprints. Well, I

thought I had a polling question, but it doesn't -- oh, okay. Can we make sure we're on the right polling. Perfect. Thank you. Okay.

Just to conclude, I wanted to reiterate the core requirements of the final rule again, and, I guess, test your knowledge. So, what are the core elements required as a part of your emergency preparedness program? And, so, it looks like we have 100%, so that's great. Again, the four core elements are emergency plan, policies and procedures, a communication plan, and a testing and training program. So, with that, I really just want to thank you all again for attending and for giving me your time this afternoon, and I will turn it back over to Kaye.

Kaye Rabel: All right. Thank you, Ronisha for the discussion on emergency preparedness. If you would like to evaluate this session, go ahead and take out your phones and text your response, or go to the Poll EV link on your tablets, iPad, or computer, and enter "A" in response to question one, "Would you like to evaluate this session," and go ahead and send your response. Remember to click on the link and follow the instructions.

Up next, a speaker from CMS will provide an overview and an update on one-third financial audits of PACE organizations. It is my pleasure to introduce from the Office of Financial Management Amando Virata.