November 13, 2018

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3346-P  
P.O. Box 8010  
Baltimore, Maryland 21244-8010

Re: CMS-3346-P – Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Dear Administrator Verma:

Trust for America’s Health (TFAH) appreciates the opportunity to submit the following comments in response to the proposed rule on promoting program efficiency, transparency, and burden reduction in the Medicare and Medicaid programs. TFAH is a nonprofit, nonpartisan organization dedicated to promoting optimal health for every person and community and makes prevention and illness and injury a national priority. As such, TFAH believes it is imperative the US healthcare system be capable of preparing for and responding to health emergencies, ranging from bioterrorist threats to serious disease outbreaks and extreme weather events. Our comments focus on the “Emergency Preparedness for Providers and Suppliers” section of the proposed rule.

Our 2017 report on emergency preparedness, *Ready or Not? Protecting the Public’s Health from Diseases, Disasters and Bioterrorism*, is the latest in a series of TFAH reports that examine our public health and healthcare systems’ capacity to respond to emergencies and identify areas of vulnerability. TFAH has also commented on proposed rules surrounding emergency preparedness in the Medicare and Medicaid programs in March 2014 (CMS-3178-P—Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers). Our comments today echo many of the comments we submitted in 2014.

We continue to believe that it is crucial to ensure that all healthcare facilities – including hospitals, primary care providers, and institutional care facilities – are well-equipped to address health emergencies when they arise. The emergency preparedness requirements have been in effect for less than a year and have not yet been given a chance to be fully implemented and evaluated. CMS should be measuring the effectiveness of this rule before making broad changes.

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to the standards. The emergency preparedness rule is a critical tool to improve the readiness of healthcare facilities and sustain the overall resilience of the healthcare sector.²

TFAH offers the following comments with these goals in mind.

**Annual Review of Emergency Preparedness Program**

TFAH encourages Centers for Medicare and Medicaid Services (CMS) to preserve the requirement for covered facilities to annually review their emergency preparedness programs instead of modifying this review requirement to occur once every two years as proposed. Emergencies are, by definition, rapidly developing and catastrophic. Annual reviews of emergency preparedness plans enable covered facilities to routinely assess their capabilities and vulnerabilities in a health systems landscape that can change dramatically in a short period of time. While we acknowledge that the proposal is intended to decrease regulatory burden, we are concerned it would increase the likelihood that facilities’ emergency preparedness plans may not keep up with changing conditions.

We agree that it is appropriate to require facilities to review their plans in the aftermath of an emergency event and are encouraged that this requirement remains in effect within the proposed rule. As we recommended in 2014, we believe this review should take place within 180 days of the emergency event and address questions like “How did emergency and communications plans, policies and procedures actually work in practice?”, “What are lessons learned?” and “How can facilities apply their experience to addressing future health threats?” Currently, there is no specific time frame during which facilities must update their emergency preparedness plans in the aftermath of an emergency event. Setting a specific time frame after an emergency event during which a review must occur ensures vulnerabilities in an emergency preparedness plan are promptly identified and mitigated. TFAH urges CMS to establish a requirement in the final rule that facilities reevaluate and appropriately update their emergency and communications plans within a designated 180-day time frame following an emergency event.

**Documentation of Cooperation Efforts**

TFAH opposes lifting the requirement that facilities document their efforts to collaborate with local, tribal, regional, state, and federal emergency preparedness officials. The proposed rule preserves the requirement for facilities to collaborate and communicate with these officials – but would remove the requirement that this outreach be documented. We strongly support maintaining the coordination requirements. However, we are concerned that removing documentation requirements will weaken accountability for this step.

CMS itself acknowledges that removing this documentation requirement would save only an estimated $7 million annually. We would note that this amount does not account for potential

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costs of the change in missed collaboration among facilities and public health agencies, and reflects a very minimal burden on individual facilities.

According to the National Health Security Preparedness Index (NHSPI), Community Planning and Engagement — how communities mobilize different stakeholders to work together during times of crisis — is one of the country’s weakest domains in preparedness, scoring a 6.0 out of a possible 10.³ This is despite community planning and engagement realizing the largest improvement in NHSPI score over the past five years among measured preparedness domains.⁴ Given the state of community planning and engagement, we ask CMS to maintain documentation requirements surrounding coordination of emergency preparedness plans.

**Annual Emergency Preparedness Training Program**

Mirroring our comments on annual review of emergency preparedness plans, TFAH urges CMS to maintain the requirement for covered facilities to conduct annual training based on their emergency preparedness plans instead of modifying this requirement to occur once every two years as proposed. We support requiring this training to be conducted when the emergency plan is significantly updated but believe that decreasing the frequency of routine training will slightly lessen regulatory burden and significantly increase the possibility that an emergency plan will fail due to lack of preparation and training. One recent survey estimates turnover rates in healthcare at 19.2 percent, with the highest rates in long-term care facilities.⁵ Moving to biennial training places these new employees at increased risk during an emergency.

On their 10 point scale, NHSPI rates Healthcare Delivery, i.e. the state of healthcare systems during everyday life, as well as in emergency situations, a 5.2 out of a possible 10.⁶ Of the six preparedness domains scored by NHSPI, Healthcare Delivery is not only the weakest, but saw the smallest amount of improvement over the past five years.⁷ While there is no substitute for real-world experience, routinely training providers on the delivery of healthcare during an emergency increases the likelihood that emergency preparedness systems operate as planned and help ensure more consistent access to healthcare during emergency events. Decreasing the required frequency of emergency preparedness training to once every two years would likely weaken this already weak preparedness domain. Accordingly, TFAH urges CMS to maintain the current annual training requirements.

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⁴ *Id.*


⁷ *Id.*
Annual Emergency Preparedness Testing

TFAH supports the proposal to give facilities more flexibility in meeting the requirement to test emergency preparedness requirements. We believe that allowing inpatient facilities to conduct a test of their choice for one of the two required annual tests is a sensible step. By allowing inpatient facilities to pick which of the various exercises available to them (a community-based full-scale exercise, an individual facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes group discussion led by a facilitator) is likely to benefit their staff, facilities can maintain emergency preparedness systems while allocating resources in a more tailored and efficient way.

TFAH also agrees with CMS’s proposal to reduce the number of required emergency preparedness exercises for outpatient facilities. Given the more limited resources available in outpatient facilities and the secondary roles outpatient facilities typically play in emergency preparedness plans when compared to inpatient facilities, two exercises per year is likely excessive where one annual exercise would suffice.

We do urge CMS to closely monitor these changes, and any potential unintended consequences, to ensure that preparedness exercises continue to be meaningful and robust.

Conclusion

We appreciate your careful consideration of our comments, and look forward to working with CMS to further strengthen emergency preparedness nationwide. If you have any questions, please contact Dara Lieberman, TFAH’s Senior Government Relations Manager at dlieberman@tfah.org or 202-864-5942.

Sincerely,

John Auerbach, MBA
President and CEO