Department of Health and Human Services
Office of Inspector General
Office of Audit Services

July 2025 | A-02-22-01019

CMS Should Take Additional Actions To Help Hospitals Prepare for a Future Emerging Infectious Disease Outbreak

REPORT HIGHLIGHTS

July 2025 | A-02-22-01019

CMS Should Take Additional Actions To Help Hospitals Prepare for a Future Emerging Infectious Disease Outbreak

Why OIG Did This Audit

- Hospitals that cannot control the spread of emerging infectious diseases within their facilities risk spreading diseases to patients, staff, and the community. This is the second OIG audit of CMS controls related to hospital preparedness for emerging infectious diseases.
- Our prior audit assessed the design and implementation of CMS controls. This audit assessed the operating effectiveness of CMS controls related to emerging infectious disease outbreaks.

What OIG Found

Although CMS took significant actions to help hospitals prepare for a future emerging infectious disease outbreak, we identified gaps in CMS controls that could negatively affect hospital preparedness during a future event with a scope and duration similar to COVID-19. Specifically:

- CMS did not ensure that surveyors were trained to cover key planning areas for an emerging infectious disease outbreak.
- CMS did not ensure that hospital emergency preparedness plans met the needs of all at-risk patient populations.
- CMS's guidance did not address the mental health of hospital frontline staff as part of hospital emergency preparedness planning.

What OIG Recommends

We made five recommendations to CMS, including that it collaborate with its emergency preparedness partners to expand surveyor training, require that hospital accreditation organization standards and survey processes cover the needs of people from all at-risk patient populations, and encourage hospitals to take into consideration the mental health of hospital frontline staff as part of emergency preparedness planning. The full recommendations appear in the report.

CMS concurred with all five recommendations, with some limitations, and described actions it plans to take in response to our recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

Hospitals that fail to control the spread of emerging infectious diseases within their facilities risk spreading a disease similar to COVID-19 or mpox to patients, staff and, ultimately, the community at large. This is the second Office of Inspector General (OIG) audit of the Centers for Medicare & Medicaid Services (CMS) controls related to hospital preparedness for emerging infectious diseases.[1] Our prior audit assessed the design and implementation of CMS controls.[2] This audit addresses the operating effectiveness of CMS controls.

OBJECTIVE

Our objective was to determine whether CMS internal controls were effective in preparing hospitals for a future emerging infectious disease outbreak.

BACKGROUND

CMS's All-Hazards Approach to Emergency Preparedness

Hospitals that participate in the Medicare and Medicaid programs must comply with Federal quality and safety standards.[3] As part of these standards, CMS in 2016 adopted a final rule that requires an all-hazards approach to emergency preparedness.[4] Under this rule, facilities are required to develop an emergency plan based on a risk assessment, develop policies and procedures, train staff, and test preparedness. Hospitals and other types of facilities have been required to implement plans since November 15, 2017.

[1] Emerging infectious diseases threaten public health, economic stability, and many everyday activities. Before COVID-19 and mpox, emerging infectious disease threats included the Ebola disease (2014), H1N1 influenza (2009), and the severe acute respiratory syndrome (SARS) outbreak of 2003.

[2] OIG, *CMS's Controls Related to Hospital Preparedness for an Emerging Infectious Disease Were Well-Designed and Implemented but Its Authority Is Not Sufficient for It To Ensure Preparedness at Accredited Hospitals* (A-02-21-01003), June 24, 2021.

[3] Social Security Act § 1861(e); 42 CFR Part 482. CMS's quality and safety standards are known as "conditions of participation."

[4] CMS, *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers,* 81 Fed. Reg. 63860 (Sept. 16, 2016), codified at 42 CFR § 482.15. An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address hazards as well as a wide spectrum of emergencies or disasters (CMS *State Operations Manual,* Appendix Z, Definitions).

In response to a recommendation in an OIG study,[5] CMS in February 2019 added "emerging infectious diseases" to the definition of the all-hazards approach because CMS "determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program."[6] See Appendix B for Federal requirements related to hospital emergency preparedness.

Standards for Internal Control in the Federal Government

Federal agencies, including CMS, are required to comply with *Standards for Internal Control in the Federal Government* (Green Book), published by the Government Accountability Office. The Green Book defines an internal control as a process used by management to help an entity achieve its objectives and provides criteria for designing, implementing, and operating an effective internal control system. Among other requirements, an agency must ensure that controls operate effectively so that objectives will be achieved. A deficiency in operation exists when a properly designed control does not operate as designed, or when the person performing the control does not possess the necessary authority or competence to perform the control effectively.

CMS Controls Related to Emerging Infectious Diseases

CMS's control objective for hospital emergency preparedness is to ensure that hospitals are prepared to maintain quality and safety and respond to risks during an emerging infectious disease outbreak.

Before the emergence of COVID-19, CMS designed and implemented the following controls to ensure that hospitals maintain quality and safety and respond to risks during an emerging infectious disease outbreak:

- written guidance such as the CMS State Operations Manual (SOM), Appendix Z, which provides emergency planning interpretive guidelines for hospitals, and CMS recommendations and best practices;

- referrals to information and technical assistance resources such as those provided by the Administration for Strategic Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS);[7]

[5] OIG, *Hospitals Reported Improved Preparedness for Emerging Infectious Diseases After the Ebola Outbreak* (OEI-06-15-00230), Oct. 16, 2018.

[6] CMS Memorandum to State Survey Agency Directors, QSO-19-06-ALL (Feb. 1, 2019).

[7] ASPR was formerly known as the Office of the Assistant Secretary for Preparedness and Response. On Mar. 27, 2025, HHS announced a restructuring plan that, among other things, would move ASPR under the Centers for Disease Control and Prevention to enhance coordination of response efforts.

- teleconferences and conference speaking engagements to communicate information or address provider questions; and

- online training through the CMS Quality, Safety & Education Portal.

After the HHS Secretary declared a public health emergency (PHE) on January 31, 2020, because of the emerging infectious disease COVID-19, CMS promptly:

- gave additional guidance to health care providers that included references to Centers for Disease Control and Prevention (CDC) guidance;

- temporarily allowed health care providers not to follow certain rules (e.g., requirements for telehealth services);

- frequently hosted teleconferences for providers and accreditation organizations (AOs) to provide information and respond to questions;

- directed State Survey Agencies (SSAs) to reprioritize survey work and perform targeted infection control surveys of certified hospitals;

- amended the SOM to expand on best practices, lessons learned, and planning considerations for emerging infectious diseases;[8]

- developed training for surveyors designed to identify noncompliance with emergency preparedness requirements that included emerging infectious disease scenarios; and

- conducted a study of hospital experiences with responding to the COVID-19 pandemic.[9]

Currently, CMS relies on several different surveys performed by SSAs and four CMS-approved AOs to ensure that it meets the control objective for hospital emergency preparedness. See Appendix C for a description of the types of surveys used by CMS.

HOW WE CONDUCTED THIS AUDIT

We identified CMS's control objective for hospital emergency preparedness of approximately 500 hospitals certified to participate in Medicare and Medicaid by SSAs and the approximately 4,200 accredited hospitals deemed certified. We then determined whether CMS controls were operating effectively to achieve that objective with respect to hospital emergency

[8] CMS Memorandum to State Survey Agency Directors, QSO 21-15-ALL (Mar. 26, 2021).

[9] Blackstock, Sheila C, Jean D. Moody-Williams, and Lee A. Fleisher. "Learnings Regarding Emergency Preparedness During the Public Health Emergency: A Mixed-Methods Study of Hospitals and Long-Term Care Facilities." *NEJM Catalyst Innovations in Care Delivery*, Aug. 24, 2022. CMS stated that it plans to use the information from this study to inform its future policy approach on emergency preparedness.

preparedness for an infectious disease outbreak. As part of determining whether CMS controls were effective in meeting CMS's control objective, we selected a nonstatistical sample of five hospitals based on locations (i.e., hospitals in different States) and numbers of COVID-19 cases resulting in death (i.e., hospitals with the most deaths).[10] We reviewed the selected hospitals' emergency preparedness programs and interviewed five SSAs associated with the hospitals and CMS to assess the effectiveness of CMS controls over hospital emergency preparedness for emerging infectious diseases.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

CMS controls generally were effective to ensure that hospitals prepare for a future emerging infectious disease outbreak. However, we identified gaps that could negatively affect hospital preparedness during a future event with a scope and duration similar to COVID-19. First, CMS did not ensure that SSA and AO surveyors were trained to cover key planning areas for an emerging infectious disease outbreak. Second, CMS did not ensure that hospital emergency preparedness plans met the needs of all at-risk patient populations. Finally, CMS's update to the SOM did not address the mental health of hospital frontline staff as part of emergency preparedness planning.

These gaps occurred due to the difficulty in comprehensively updating training, interpretive guidelines, recommendations, and best practices in response to an emerging infectious disease with a scope and duration similar to COVID-19. If CMS does not correct these gaps, hospitals may not be prepared to maintain quality and safety during a future emerging infectious disease outbreak.

CMS DID NOT ENSURE THAT SURVEYORS WERE TRAINED TO COVER KEY PLANNING AREAS FOR AN EMERGING INFECTIOUS DISEASE OUTBREAK

ASPR publishes guidance that identifies key planning areas to help hospitals and other providers prepare for an emerging infectious disease outbreak. One such guide, published November 30,

[10] During our audit period, mpox emerged and was declared a PHE in the United States. Hospitals provided us with mpox response actions relating to patient placement, personal protective equipment, waste management, environmental infection control, isolation of exposed patients, and community outreach. Hospitals also provided the status of mpox testing, vaccines, and treatments. We noted that hospitals at the time of our audit were well prepared and not overwhelmed with a surge of mpox-infected inpatients. Also, no mpox-related deaths had been reported at the hospitals we reviewed.

2020, and updated September 20, 2021, was the Hospital Operations Toolkit for COVID-19, which included two key planning areas: (1) surge capacity and (2) infection prevention and control. Appendix D provides more information on these key planning areas. To plan for a future emerging infectious disease, CMS expanded its guidelines for SSAs to generally cover these key planning areas and referred to ASPR guidance for resources.[11]

One control that CMS uses to maintain safety and quality involves exercising oversight of SSA training of surveyors. Surveyors are trained to evaluate provider compliance with CMS's conditions of participation, including emergency preparedness requirements.

CMS did not ensure that surveyors were trained to cover key planning areas for an emerging infectious disease outbreak. Specifically, CMS's oversight of SSAs and AOs did not ensure that surveyors were trained to cover (1) surge capacity and (2) infection prevention and control for an emerging infectious disease outbreak. The five SSAs we interviewed did not provide documentation showing that their surveyors had been trained to cover these key planning areas. Although CMS requires SSA surveyors to take an emergency preparedness basic training course, the course does not cover these key planning areas. Also, CMS has not ensured that AO surveyors cover the key planning areas. CMS oversight of AO survey processes is based on what is required for SSA survey processes.[12]

Therefore, CMS may not be assured that hospitals will maintain quality and safety and respond to risks during an emerging infectious disease outbreak.

CMS DID NOT ENSURE THAT HOSPITAL EMERGENCY PREPAREDNESS PLANS MET THE NEEDS OF ALL AT-RISK PATIENT POPULATIONS

CMS considers preparedness for an emerging infectious disease outbreak to include plans that address a hospital's patient population, including populations at risk.[13] For accredited hospitals, CMS controls include the approval of AO standards and survey processes to ensure that hospital emergency preparedness plans meet the needs of all at-risk patient populations.

CMS did not ensure that hospital emergency preparedness plans met the needs of people from all at-risk patient populations. The standards for all four AOs require hospitals to address patient populations, including populations at risk. However, the AOs' standards and survey processes do not incorporate CMS's definition of populations at risk. CMS's accreditation review process did not correct the definition's omission from the AOs' standards and survey processes.

[11] CMS QSO 21-15-ALL.

[12] 42 CFR § 488.5(a)(4)(ii).

[13] CMS defines at-risk populations to include all populations discussed in the National Response Framework and Public Health Service Act definitions (81 Fed. Reg. 63860, 63875 (Sept. 16, 2016)).

As a result, none of the emergency preparedness plans for the five hospitals we reviewed addressed all at-risk patient populations, as defined by CMS.

CMS's GUIDANCE DID NOT ADDRESS THE MENTAL HEALTH OF HOSPITAL FRONTLINE STAFF AS PART OF EMERGENCY PREPAREDNESS PLANNING

The COVID-19 PHE was in effect for more than 3 years and was the longest duration emergency event since CMS finalized the emergency preparedness rule in 2016.[14] Research shows that the PHE took a heavy toll on the mental health and well-being of hospital frontline staff.[15, 16] Some of these workers may suffer post-traumatic stress disorder symptoms for long periods after treating COVID-19 patients.[17] Stressors among frontline workers during the COVID-19 PHE included:[18,19]

- experiencing an unprecedented number of patient deaths,
- informing family members about the deaths of loved ones who could not be with family,
- illness or death among colleagues,
- fears of getting infected and infecting loved ones,
- longer than usual working periods,
- being deployed to work outside job specialties or disciplines, and
- shortages of personal protective equipment.

[14] CMS Proposed Rule, Healthcare System Resiliency and Modernization (CMS-3426-P).

[15] Hendrickson, Rebecca C., Roisín A Slevin, Katherine D Hoerster, et al. "The Impact of the COVID-19 Pandemic on Mental Health, Occupational Functioning, and Professional Retention Among Health Care Workers and First Responders." *Journal of General Internal Medicine*, Feb. 2022.

[16] Bradley, Meredith, and Praveen Chahar. "Burnout of healthcare providers during COVID-19." *Cleveland Clinic Journal of Medicine*, July 2020.

[17] Restauri, Nicole, and Alison D Sheridan. "Burnout and Posttraumatic Stress Disorder in the Coronavirus Disease 2019 (COVID-19) Pandemic: Intersection, Impact, and Interventions." *Journal of the American College of Radiology*, July 2020.

[18] Arnetz, Judith E., Courtney M. Goetz, Bengt B. Arnetz, Eamonn Arble. "Nurse Reports of Stressful Situations during the COVID-19 Pandemic Qualitative Analysis of Survey Responses." *International Journal of Environmental Research and Public Health,* Nov. 2020.

[19] Jervis, Rick, "'Death is our greeter': Doctors, nurses struggle with mental health as coronavirus cases grow," *USA Today*, May 5, 2020.

Additionally, a CMS study of provider experiences in responding to the COVID-19 PHE found that support strategies used by providers to maintain staff resilience were critical for supporting an effective response as staff fatigue and burnout increased during the PHE.[20] Thus, CMS should encourage hospitals to include mental health support as part of their emergency preparedness planning. For example, CMS could communicate these support strategies through recommendations and best practices to hospitals through updates to the SOM.

Although CMS updated the SOM to share lessons learned during the COVID-19 PHE, the update did not address the mental health of hospital frontline staff. CMS officials said that the SOM does not address the mental health of hospital staff because they do not believe CMS has authority to require hospitals to provide mental health services to staff. We noted that CMS has used the SOM to communicate recommendations and best practices that were not requirements; therefore, CMS may be able to issue guidance to address the mental health of hospital frontline staff as part of emergency planning in a future iteration of the SOM.[21]

If hospitals do not address the mental health of hospital frontline staff during an emerging infectious disease, they may not have sufficient staff in good health during and after an outbreak, which could have a negative effect on the quality and safety of care provided.

CONCLUSION

Although CMS controls are generally effective, hospitals may not be prepared to maintain quality and safety during a future emerging infectious disease outbreak that shares the scope and duration of the COVID-19 outbreak. CMS should therefore close the gaps we have identified in the areas of hospital surveyor training, addressing all at-risk patient populations in emergency planning, and addressing the mental health of frontline hospital staff to help hospitals be better prepared for a future emerging infectious disease outbreak.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- collaborate with its emergency preparedness partners to expand SSA surveyor training to include key planning areas related to emerging infectious diseases consistent with CMS interpretive guidelines;

- require AO surveyor training to include key planning areas related to emerging infectious diseases comparable to those included for SSA surveyors;

[20] Blackstock, Sheila C, Jean D. Moody-Williams, and Lee A. Fleisher. "Learnings Regarding Emergency Preparedness During the Public Health Emergency: A Mixed-Methods Study of Hospitals and Long-Term Care Facilities." *NEJM Catalyst Innovations in Care Delivery*, Aug. 24, 2022.

[21] For example, CMS's memorandum QSO 21-15-ALL, which was issued on Mar. 26, 2021, provided guidance on best practices and lessons learned.

- as part of CMS's accreditation review process, require AOs' hospital emergency preparedness standards to include addressing the needs of individuals from all at-risk patient populations;

- require that AOs' hospital survey processes include verifying that hospital emergency plans address the needs of all at-risk patient populations; and

- encourage hospitals to take into consideration the mental health of hospital frontline staff as part of emergency preparedness planning.

CMS COMMENTS AND OIG RESPONSE

CMS concurred with all five of our recommendations with some limitations and stated that it will continue to take actions within its statutory and regulatory authorities related to hospital oversight. CMS disagreed with our finding that it did not ensure that surveyors were trained to evaluate provider compliance with emergency preparedness requirements. Specifically, CMS noted that hospital surveyors were trained to evaluate compliance with the required CMS conditions of participation and that our finding was based on ASPR's COVID-19 hospital toolkit guidance. We acknowledge that our finding was based on the key planning areas identified by ASPR and conclude that hospital surveyors would benefit from further training on these areas, which CMS has already added to the SOM. CMS also stated that it will continue to collaborate with ASPR on updates to trainings, as needed.

CMS stated that it will review guidance for AOs seeking to renew their deemed status to ensure greater consistency with the regulatory requirement for hospital emergency plans to include plans for at-risk patient populations.[22, 23]

Regarding our recommendation that CMS encourage hospitals to take into consideration the mental health of hospital frontline staff as part of emergency preparedness planning, CMS stated that it will encourage hospitals to seek out resources from other Federal agencies and external entities that work to address the mental health of medical staff.

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding technical comments, are included as Appendix E.

[22] As described earlier, CMS relies on surveys performed by SSAs and four CMS-approved AOs to ensure that it meets the control objective for hospital emergency preparedness. CMS-approved AOs must apply to CMS for approval to conduct deemed status surveys.

[23] Deemed status means that CMS has certified a provider or supplier for Medicare participation based on all of the following criteria having been met: the provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national AO under the applicable Medicare accreditation program; the AO has recommended the provider or supplier to CMS for Medicare participation; CMS has accepted the AO's recommendation; and CMS finds that all other participation requirements have been met (42 CFR § 488.1).

After reviewing CMS's comments, we believe that the actions CMS described, when fully executed, should resolve all five of our recommendations.

We thank CMS for its cooperation during this audit.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We identified CMS's control objective for hospital emergency preparedness of approximately 500 hospitals certified to participate in Medicare and Medicaid by SSAs and approximately 4,200 accredited hospitals deemed to be certified.[24] We then determined whether CMS controls were operating effectively to achieve that objective with respect to hospital emergency preparedness for an infectious disease outbreak. As part of determining whether CMS's internal controls were effective in meeting CMS's control objective, we selected a nonstatistical sample of five hospitals based on locations (i.e., hospitals in different States) and numbers of COVID-19 cases resulting in death (i.e., hospitals with the most deaths). We reviewed the selected hospitals' emergency preparedness programs and conducted interviews with the five SSAs associated with the hospitals and CMS to assess the effectiveness of CMS controls over hospital emergency preparedness for emerging infectious diseases.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We conducted our audit work from July 2022 through August 2024.

METHODOLOGY

To accomplish our objectives, we:

- reviewed Federal regulations;
- reviewed CMS guidance, correspondence, policies, training, and targeted infection control survey data;
- reviewed a CMS study on providers' experiences in responding to the COVID-19 pandemic;
- selected a nonstatistical sample of five hospitals based on their locations (hospitals in five States covering four regional, core-based statistical areas) and on the number of

[24] Certification means a determination made by the SSA that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements (42 CFR § 488.1).

COVID-19 cases that resulted in patient deaths;[25]

- interviewed hospital emergency management directors and reviewed hospital emergency preparedness programs, including emergency preparedness plans, risk analyses, policies, procedures, communication plans, and training programs to determine compliance with Federal emergency preparedness requirements specifically related to emerging infectious diseases;

- interviewed hospital executives and reviewed hospital data on COVID-19 cases and deaths;

- provided written questions and reviewed responses from hospitals regarding their responses to mpox;[26]

- provided written questions, reviewed responses, and conducted interviews with SSAs associated with five hospitals to determine the operating effectiveness of CMS internal controls;

- reviewed AOs' standards and survey processes; and

- discussed our results with CMS officials.

[25] A core-based statistical area has a large population nucleus, or urban area, and adjacent communities that have a high degree of integrating with that nucleus.

[26] The HHS Secretary declared mpox a PHE between Aug. 4, 2022, and Jan. 31, 2023.

APPENDIX B: FEDERAL REQUIREMENTS RELATED TO EMERGENCY PREPAREDNESS

Section 1861(e) of the Social Security Act (the Act) requires hospitals that participate in the Medicare and Medicaid programs to comply with Federal quality and safety standards. CMS's quality and safety standards are included in CMS's "conditions of participation (CoP)." Federal regulations (42 CFR § 482.15) establish the emergency preparedness CoP for acute care hospitals.

Section 1864(a) of the Act requires that the HHS Secretary enter into an agreement with States under which SSAs determine whether hospitals meet the Medicare CoP.

Section 1865(a) of the Act provides that if a hospital is accredited by a national AO recognized by the HHS Secretary, it may be deemed to have met the CoP.

42 CFR § 488.5(a) provides the requirements AOs must meet to be approved by CMS, including:

- 42 CFR § 488.5(a)(3), which requires that AOs furnish CMS with a detailed crosswalk that identifies each applicable Medicare CoP and the exact language of each organization's comparable accreditation standards, and

- 42 CFR § 488.5(a)(4), which requires that each AO furnish CMS with a detailed description of the survey process to confirm that hospitals meet or exceed Medicare program requirements.

Moreover, 42 CFR § 488.8 provides the requirements for ongoing reviews of AOs.

APPENDIX C: MEDICARE AND MEDICAID HOSPITAL SURVEYS

As a component of its oversight of hospitals, CMS relies on a variety of survey types to assess hospitals' compliance with quality and safety requirements. In addition to assessing compliance, a survey may serve to educate a hospital (e.g., about how to prepare for a surge of infected patients). The surveys are conducted at the approximately 4,700 hospitals certified to participate in Medicare and Medicaid by SSAs or deemed to be certified because they are accredited by an AO. CMS may also elect to have its own surveyors perform a survey at any time.

ROUTINE SURVEYS

An SSA may certify certain hospitals' compliance with Medicare and Medicaid quality and safety requirements after conducting an inspection known as a routine survey. Hospitals that undergo a routine survey conducted by an SSA, which represent about 10 percent of all Medicare and Medicaid hospitals, are referred to as "certified hospitals."

Alternatively, hospitals may voluntarily apply for and receive accreditation from one of four private AOs, which are approved by CMS. Hospitals accredited by private AOs, which comprise about 90 percent of all Medicare and Medicaid hospitals, are referred to as "accredited hospitals."

CMS pays SSAs for survey work and prioritizes each SSA's workload. SSAs currently perform routine surveys of certified hospitals approximately once every 5 years. Each accredited hospital pays a fee to one of the four AOs. An AO must perform a reaccreditation survey at least once every 3 years (a triennial survey).

COMPLAINT SURVEYS

As part of CMS's oversight of certified and accredited hospitals, CMS directs SSAs to perform complaint surveys. Specifically, an applicable SSA performs a complaint survey after a complaint is made against a certified hospital. The SSA performs a similar survey at an accredited hospital after a complaint is made that would, if the complaint's allegation is proven true, prove that the hospital was not in substantial compliance with a condition of participation. SSAs perform about 2,800 complaint surveys per year. Many surveys have identified infection control deficiencies.

VALIDATION SURVEYS

To measure the effectiveness of AO hospital surveys, CMS ensures that validation surveys are performed each year at selected accredited hospitals. CMS selects a representative sample of accredited hospitals each year for a validation survey. Before October 2023, CMS validated an AO's routine survey of an accredited hospital by directing an associated SSA to perform a validation survey within 60 days of completion of an AO's routine and/or triennial survey of an

accredited hospital. Since October 2023, CMS has used contractors instead of SSAs to perform validation surveys. During these surveys, which are now called "direct observation validation surveys," a contractor's surveyors observe AO surveyors during a routine and/or triennial survey.[27]

OTHER SURVEYS INCLUDING SPECIAL SURVEYS

CMS also requires other types of surveys. Some of these surveys are called "special surveys" or given a specific name and put in place for a limited time. For example, CMS suspended routine surveys for a period during the COVID-19 PHE and required focused infection control surveys which were performed by SSAs at certified and accredited hospitals. CMS developed the focused infection control survey at the beginning of the COVID-19 PHE to help surveyors and hospitals quickly focus on and absorb critical infection prevention and control practices for combating COVID-19. After CMS believed hospitals had incorporated COVID-19 management strategies into their infrastructure and operations, CMS discontinued focused infection control special surveys and returned to a normal survey protocol.

[27] CMS Memorandum to State Survey Agency Directors, QSO Admin Info: 23-14-NLTC (Sept. 6, 2023).

APPENDIX D: HOSPITAL OPERATIONS TOOLKIT FOR COVID-19: CAPACITY AND INFECTION PREVENTION AND CONTROL

ASPR created the Technical Resources, Assistance Center, and Information Exchange (TRACIE) to meet the needs of those working in disaster medicine, health care system preparedness, and PHE preparedness. One TRACIE resource was the Hospital Operations Toolkit for COVID-19, which included separate sections for two key planning areas—Capacity, and Infection Prevention and Control.[28]

CAPACITY

ASPR created three documents within the toolkit's Capacity section to help hospitals manage surge capacity. The documents were:

- "Space," which discussed maximizing inpatient space, balancing loads with other hospitals, critical care, hospital-based alternative care sites, nontraditional facility use, and adjusting services. The document referenced additional resources.

- "Staffing," which described challenges for staff in critical care nursing, respiratory therapy, logistics, and environmental services. The document discussed several surge staffing options and referenced additional resources.

- "Supply Chain," which discussed and referenced additional resources for general supply chain issues, selection and acquisition, allocation and inventory management, and preservation.

INFECTION PREVENTION AND CONTROL

ASPR stated that the health and safety of staff and patients depend on strong infection prevention and control efforts. ASPR further stated that the hierarchy of controls developed by CDC offers a framework to protect those in a hospital. ASPR described these controls and referenced additional resources in four Toolkit documents:

- "Elimination and Substitution Controls," which referenced additional resources for reducing exposure to COVID-19 in the workplace.

[28]After the issuance of our draft report, ASPR removed many COVID-19-specific resources from its website, including the Hospital Operations Toolkit for COVID-19. In March 2025, ASPR piloted an online guidebook at https://asprtracie.hhs.gov/HRROG that includes a "Surge Concepts" chapter that covers the Capacity topics described in this appendix. Also, CDC maintains the infection prevention and control framework described by ASPR at Hierarchy of Controls (accessed May 29, 2025).

- "Engineering Controls," which discussed modifying physical workspaces to separate individuals from COVID-19 and reduce their reliance on other controls (e.g., personal protective equipment). The document referenced additional resources.

- "Administrative Controls," which discussed policies, procedures, and process changes that reduce an individual's exposure to an identified hazard. The document referenced additional resources.

- "Personal Protective Equipment," which discussed protecting hospital staff from occupational exposure to COVID-19.

APPENDIX E: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

Date: November 21, 2024

To: Juliet T. Hodgkins
Principal Deputy Inspector General

From: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

Subject: Office of Inspector General Draft Report: CMS Should Take Additional Actions To Help Hospitals Prepare for a Future Emerging Infectious Disease Outbreak (A-02-22-01019)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report.

Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to be eligible to receive Medicare payments. The CoPs cover a wide array of topics, including an emergency preparedness requirement that directs hospitals to implement an emergency preparedness program based on an all-hazards approach. This integrated emergency preparedness planning focuses on capacities and capabilities that are critical to preparedness for a wide range of emergencies or disasters. This approach is specific to the location and patient population served by the provider and considers the type of hazards most likely to occur in those areas.

In 2016, CMS published the *Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers* Final Rule (CMS-3178-F) (81 FR 63860, Sept. 16, 2016) that applies to all provider and supplier types, including hospitals. While the standards are adjusted to reflect the characteristics of each type of provider and supplier, they all focus on the same common planning areas and reflect an all-hazards approach, which includes planning for emerging infectious diseases. Infection control is always an emergency preparedness priority, and in 2017, to highlight the importance of infection control, CMS worked with the Centers for Disease Control and Prevention (CDC) to develop publicly available surveyor training that is also used by providers titled, *Universal Infection Prevention and Control.*[1] The course provides general infection control practices and information related to Infections with High Mortality Rates, such as Ebola and the Flu, which contain elements of preparing for a surge as well as basic infection control practices that are relevant for all infectious diseases. Additionally, in February 2019, CMS added additional guidance to the State Operations Manual, Appendix Z –

[1] QSEP, Universal Infection Prevention and Control (UIPC). Accessed at https://qsep.cms.gov/pubs/ClassInformation.aspx?cid=0CMSUIPC_ONL.

Emergency Preparedness, to specifically include emerging infectious diseases. Furthermore, CMS links providers to the Assistant Secretary for Preparedness and Response (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE) as a resource for how-to guides, tools, etc., which has also been referenced in CMS guidance and presentations since 2016. ASPR TRACIE serves as a public resource for all healthcare preparedness, and has tools and resources specific to infectious diseases, which are continuously revised and updated. In March 2021, CMS further updated Appendix Z to include additional planning considerations and preparedness guidance which expanded on emerging infectious diseases.[2] Subsequently, CMS updated the Emergency Preparedness Basic Course[3] and Basic Hospital Surveyor Training[4] course that State Survey Agency (SSA) surveyors are required to complete.

As part of CMS's efforts to oversee hospital compliance with Federal participation requirements, CMS works in partnership with SSAs and Accrediting Organizations (AOs) to conduct onsite hospital surveys. These surveys are accomplished through observations, interviews, and document/record reviews. AOs are required by our regulations at 42 C.F.R. §488.5 to have comparable survey processes and standards that either meet or exceed those of CMS, as well as meet other specified requirements. In February 2024, CMS issued a proposed rule for *Strengthening Oversight of AOs and Preventing AO Conflict of Interest, and Related Provisions* (CMS-3367-P) (89 FR 11996, Feb. 15, 2024). Changes in this Notice of Proposed Rulemaking (NPRM) include holding AOs accountable to the same standards as SSAs and improving consistency and standardization in surveys nationwide. The NPRM more closely aligns AO survey activity requirements and staff training with those of SSAs, including a proposal to require AO surveyors to complete the CMS basic training course that SSA surveyors are required to complete.

OIG's report recommends additional actions CMS should take to help hospitals prepare for a future emerging infectious disease outbreak. CMS agrees that more can be done to oversee hospitals, and we continue to take actions that are within our statutory and regulatory authority. Multiple agencies and outside entities share in the responsibilities of overseeing and supporting providers in preparing for future outbreaks, and CMS partners with other agencies routinely to share expertise. CMS disagrees with the OIG's finding that CMS did not ensure that surveyors were trained to evaluate provider compliance with emergency preparedness requirements. This finding is based on ASPR toolkits, rather than the requirements in CMS's CoPs and related guidance. CMS developed and has continued to engage with ASPR on every iteration of Appendix Z and the Emergency Preparedness Basic Course surveyor training, which all SSAs are required to complete. This training helps surveyors gain proficiency in surveying all affected participating providers and certified suppliers for compliance with their individual CMS emergency preparedness requirements. The training includes information on overarching

[2] CMS Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, QSO-21-15-ALL. Updated Guidance for Emergency Preparedness-Appendix Z of the State Operations Manual (SOM). March 26, 2021. Accessed at https://www.cms.gov/files/document/qso-21-15-all.pdf.
[3] QSEP, Emergency Preparedness Basic Training (EP). Accessed at https://qsep.cms.gov/pubs/ClassInformation.aspx?cid=0CMSEmPrep_ONL
[4] QSEP, Hospital Basic Training (HBT). Accessed at https://qsep.cms.gov/pubs/ClassInformation.aspx?cid=0CMSHBT_Online

concepts of emergency preparedness requirements and guidance from Appendix Z. Furthermore, in 2023, CMS released the Emergency Preparedness Surveyor Skills training for State surveyors, which uses case scenarios and responses related to how to survey for certain areas of emergency preparedness, including the facility's testing program, use of volunteers, and emerging infectious disease training. CMS's training also links to ASPR TRACIE resources created from CMS guidance, including provider-specific checklists for use by providers, suppliers, and surveyors.

CMS thanks the OIG for its efforts on this issue and looks forward to working collaboratively on this and other issues in the future. OIG's recommendations and CMS's responses are below.

OIG Recommendation

CMS should collaborate with ASPR and ASPR's partners to expand SSA surveyor training to include key planning areas related to emerging infectious diseases consistent with CMS interpretative guidelines.

CMS Response

CMS concurs with this recommendation to the extent that we have already collaborated with ASPR and will continue to do so. SSA surveyors must survey to the requirements of CMS's CoPs, and CMS trainings reflect the content of these requirements. CMS regularly collaborates with ASPR to develop guidance and training materials for emergency preparedness. In 2017, CMS developed Appendix Z in collaboration with ASPR and several emergency management experts. CMS has also developed the Emergency Preparedness Basic Course and surveyor skills training, which focuses on the emergency preparedness requirements and examples of differing situations under the all-hazards approach. Surveyor guidance and training include information on emergency staffing strategies and surge planning for a variety of events, including infectious disease outbreaks. The training and Appendix Z also link to ASPR TRACIE resources created from CMS guidance, including provider-specific checklists for use by providers, suppliers, and surveyors. CMS will continue to collaborate with ASPR as updates to the training are needed.

OIG Recommendation

CMS should require AO surveyor training to include key planning areas related to emerging infectious diseases comparable to those included for SSA surveyors.

CMS Response

CMS concurs with this recommendation with the noted limitation. CMS issued a proposed rule for *Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions* (CMS-3367-P). In this NPRM, CMS proposed that AO surveyors be required to take the CMS online surveyor basic training courses for each provider and supplier type they survey. CMS can only implement this recommendation if these policies in the AO NPRM are finalized. If finalized, CMS will look for opportunities to improve consistency among all surveying entities through training, guidance, monitoring, and direct observation validation surveys.

OIG Recommendation

CMS should as part of CMS's accreditation review process, require AOs' hospital emergency preparedness standards to include addressing the needs of individuals from diverse cultures and racial and ethnic backgrounds.

CMS Response

CMS concurs with this recommendation with the noted limitation. AOs are required by our regulations at 42 C.F.R. §488.5 to have comparable survey processes and standards that either meet or exceed those of CMS, as well as meet other specified requirements. CMS will review AO guidance in future applications for deeming renewal to ensure further consistency with meeting the regulatory requirement for patients at risk consistent with 42 C.F.R. §482.15(a)(3).CMS issued a proposed rule for *Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions* (CMS-3367-P). Changes in this NPRM include holding AOs accountable to the same standards as SSAs and improving consistency and standardization in surveys nationwide. The NPRM more closely aligns AO survey activity requirements and staff training with those of SSAs. CMS will look for opportunities to improve consistency among all surveying entities through training, guidance, monitoring, and direct observation validation surveys.

OIG Recommendation

CMS should require that AOs' hospital survey processes include verifying that hospital emergency plans address the needs of persons at risk, including individuals from diverse cultures and racial and ethnic backgrounds.

CMS Response

CMS concurs with this recommendation with the noted limitation. AOs are required by our regulations at 42 C.F.R. §488.5 to have comparable survey processes and standards that either meet or exceed those of CMS, as well as meet other specified requirements. CMS requires SSAs who are responsible for surveying hospitals to ensure they are meeting the regulatory requirement for having emergency plans that address the needs of patients at risk consistent with 42 C.F.R. §482.15(a)(3). CMS issued a proposed rule for *Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions* (CMS-3367-P). Changes in this NPRM include holding AOs accountable to the same standards as SSAs and improving consistency and standardization in surveys nationwide. The NPRM more closely aligns AO survey activity requirements and staff training with those of SSAs. CMS will review AO guidance in future applications for deeming renewal to ensure further consistency with meeting the regulatory requirement for patients at risk consistent with 42 C.F.R. §482.15(a)(3).

OIG Recommendation

CMS should encourage hospitals to take into consideration the mental health of hospital frontline staff as part of emergency preparedness planning.

CMS Response

CMS concurs with this recommendation. CMS will encourage hospitals to seek out resources from agencies such as SAMHSA and ASPR and external entities that work to address the mental health of medical staff.

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U.S. Department of Health and Human Services
Office of Inspector General
Public Affairs
330 Independence Ave., SW
Washington, DC 20201

Email: Public.Affairs@oig.hhs.gov