

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**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**

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June 2021
A-02-21-01003

Office of Inspector General

<https://oig.hhs.gov>

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Report in Brief

Date: June 2021

Report No. A-02-21-01003

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Hospitals that cannot control the spread of emerging infectious diseases within their facilities risk spreading a disease such as COVID-19 to patients and staff. OIG therefore developed a plan to assess the Centers for Medicare & Medicaid Services' (CMS's) controls related to hospital preparedness for emerging infectious diseases.

The objective of this audit was to determine whether CMS designed and implemented effective internal controls related to hospital preparedness for emerging infectious diseases such as COVID-19.

How OIG Did This Audit

We reviewed the design and implementation of CMS's controls regarding the approximately 500 hospitals certified to participate in Medicare and Medicaid by State survey agencies under contract with CMS. We also reviewed CMS's controls regarding the approximately 4,200 hospitals known as accredited hospitals because they have joined a CMS-approved program operated by a private accreditation organization.

We limited the scope of our audit to the design and implementation of CMS's controls.

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

What OIG Found

CMS's controls were well-designed and implemented, but CMS's authority is not sufficient for it to fulfill its responsibility to ensure that accredited hospitals would maintain quality and safety during an emerging infectious disease emergency. Specifically, although CMS announced in February 2019 that it was critical for all hospitals to plan for emerging infectious diseases, CMS could not determine that all accredited hospitals updated their emergency preparedness plans to include this planning until 2022 due to accreditation organizations' quality and safety inspection cycles. Further, when COVID-19 emerged in the United States, CMS requested (but could not require) accreditation organizations to perform special targeted infection control surveys to help accredited hospitals prepare for COVID-19 patients. Accreditation organizations performed no such special surveys and, as of August 17, 2020, State survey agencies only performed these surveys at about 13 percent of accredited hospitals and had not performed any in 13 States because of CMS's limited authority over accredited hospitals. As a result of these limitations, CMS could not ensure that accredited hospitals would continue to provide quality care and operate safely during the COVID-19 emergency, and cannot ensure quality and safety at accredited hospitals when a future emerging infectious disease threatens the United States.

What OIG Recommends and CMS Comments

We recommend that CMS make regulatory changes to allow it to require accreditation organizations to perform special surveys after it issues new participation requirements or guidance and during a public health emergency to address the risks presented by the emergency.

In written comments on our draft report, CMS concurred with our recommendation. CMS also indicated that, in March 2021, it updated its *State Operations Manual* to include additional planning considerations and preparedness guidance that expanded on emerging infectious diseases.

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INTRODUCTION

WHY WE DID THIS AUDIT

Hospitals that cannot control the spread of emerging infectious diseases within their facilities risk spreading a disease such as COVID-19 to patients and staff. The Office of Inspector General (OIG) therefore developed a plan to assess the Centers for Medicare & Medicaid Services' (CMS's) controls related to hospital preparedness for emerging infectious diseases. This audit assesses the design and implementation of CMS's controls.

OBJECTIVE

Our objective was to determine whether CMS designed and implemented effective internal controls related to hospital preparedness for emerging infectious diseases such as COVID-19.

BACKGROUND

The Emergency Preparedness Rule and Emerging Infectious Diseases

Hospitals that participate in the Medicare and Medicaid programs must comply with Federal quality and safety standards.¹ In September 2016, CMS adopted a final rule (the Emergency Preparedness Rule) as part of these standards that requires an all-hazards approach to emergency preparedness.² Under this rule, providers were 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 were required to implement their plans by November 15, 2017.

On February 1, 2019, CMS added "emerging infectious diseases" to the definition of the all-hazards approach because it "determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program."³ Emerging infectious diseases threaten public health, economic stability, and many normal life activities.⁴ Previous

¹ Social Security Act § 1861(e); 42 CFR Part 482. CMS's quality and safety standards are known as the "conditions of participation."

² *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 those hazards as well as a wide spectrum of emergencies or disasters (CMS *State Operations Manual*, Appendix Z, Definitions).

³ CMS Memorandum to State Survey Agency Directors, QSO-19-06-All (Feb. 1, 2019).

⁴ Morens D.M., Fauci, A.S., "Emerging Infectious Diseases: Threats to Human Health and Global Stability," *Public Library of Science Pathogens* (July 2013). Available online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3701702>. Accessed on Mar. 5, 2021.

emerging infectious disease threats included severe acute respiratory syndrome (SARS) and the H1N1 influenza pandemic in 2009.⁵ CMS expected hospitals to add emerging infectious diseases to their plans during their next annual plan update occurring after February 1, 2019.⁶ Thus, CMS expected that some hospitals would not update their plans until February 1, 2020.

Standards for Internal Control in the Federal Government

Federal agencies, including CMS, are required to comply with the Government Accountability Office's (GAO's) *Standards for Internal Control in the Federal Government* (Green Book). Internal control is a process used by management to help an entity achieve its objectives. GAO's standards provide criteria for designing, implementing, and operating an effective internal controls system. Among other requirements, an agency must design control activities to achieve objectives and respond to risks.

CMS's Quality and Safety Oversight Controls

As a component of its oversight of hospitals, CMS relies on a variety of survey types to ensure hospitals' compliance with quality and safety requirements. The surveys are conducted at the approximately 4,700 hospitals certified to participate in Medicare and Medicaid by State survey agencies or deemed to be certified because they are accredited by a private organization.⁷

Routine Surveys

A State survey agency may certify certain hospitals' compliance with Medicare and Medicaid's quality and safety requirements after conducting an inspection known as a routine survey.⁸ We refer to these hospitals, which represent about 10 percent of all Medicare and Medicaid hospitals, as "certified hospitals."

Alternatively, hospitals may voluntarily apply for and receive accreditation from one of four private accreditation organizations, which includes routine surveys by the organization, if CMS

⁵ See preceding footnote.

⁶ Each hospital had its own update schedule depending on when it created its plan. On Feb. 1, 2019, CMS required hospitals to update their plans annually. On Sept. 30, 2019, CMS revised this requirement to at least every 2 years (84 Fed. Reg. 51732, 51817 (Sept. 30, 2019)).

⁷ The number of Medicare and Medicaid hospitals was current as of the beginning of our fieldwork and does not include the approximately 1,350 critical-access hospitals, which are CMS-designated hospitals with no more than 25 beds that meet certain other requirements.

⁸ The Social Security Act (the Act) § 1864(c).

has approved the program as meeting or exceeding CMS’s quality and safety requirements.⁹ We refer to these hospitals, which compose about 90 percent of all Medicare and Medicaid hospitals, as “accredited hospitals.”

If a routine hospital survey (i.e., quality and safety inspection) by a State survey agency or accreditation organization identifies deficiencies, the hospital must take corrective action.¹⁰ In addition to ensuring compliance, the survey may serve to educate the hospital (e.g., it could educate the hospital about how to prepare for a surge of infected patients).

CMS pays State survey agencies for their survey work and prioritizes their workload.¹¹ CMS informed us that State survey agencies currently perform routine surveys of certified hospitals approximately once every 5 years. Accredited hospitals pay a fee to one of the four accreditation organizations. Accreditation organizations must perform reaccreditation surveys at least once every 3 years (triennial surveys).¹²

Complaint Surveys

As part of its oversight of certified and accredited hospitals, CMS directs State survey agencies to perform complaint surveys.¹³ Specifically, the applicable State survey agency performs one of these surveys when a complaint is made against a certified hospital.¹⁴ The State survey agency performs a similar survey at an accredited hospital when a complaint is made that would, if the allegation were true, prove that the hospital was not in substantial compliance with a participation requirement.¹⁵ State survey agencies perform about 2,800 complaint surveys per year, many of which have identified infection control deficiencies.

⁹ The Act § 1865(a). CMS “deems” an accredited hospital to be certified to participate in Medicare and Medicaid when it applies for and receives accreditation from a program that CMS has approved. 42 CFR § 488.1 (deemed status).

¹⁰ 42 CFR § 488.28.

¹¹ The Act § 1864(b). CMS directs 80 percent of its survey budget to oversight of long-term care facilities. The remaining 20 percent is available for oversight of all remaining provider types, including hospitals.

¹² Reaccreditation surveys would not be expected to cover all hospitals’ compliance with new guidance related to a quality or safety requirement that is issued in 2019 until 2022.

¹³ The Act § 1864(a).

¹⁴ The State survey agency performs a survey for those that fit specific criteria, such as a complaint alleging non-compliance with a condition of participation. See *State Operations Manual* (Pub. 100-07), Chapter 5.

¹⁵ These complaints may result in “immediate jeopardy” or other “condition-level” deficiencies. We refer to these complaints that allow CMS to direct State survey agencies to conduct surveys as “sufficiently serious complaints.” Deficiencies that would not cause the hospital to be out of substantial compliance are known as “standard-level” deficiencies. Standard level-deficiencies at accredited hospitals remain within the jurisdiction of the accreditation organization, which performs surveys for complaints that could result in a standard-level deficiency.

Validation Surveys

To validate accreditation organization routine surveys of accredited hospitals, CMS directs State survey agencies to perform about 100 validation surveys per year. These surveys are performed as a second check, after an accreditation organization has performed a routine triennial survey at an accredited hospital.¹⁶ About 40 percent of validation surveys each year have identified at least one deficiency not found during the triennial surveys.¹⁷ Many validation surveys have identified infection control deficiencies. Other than these validation surveys, CMS may not direct a State survey agency to survey an accredited hospital unless there is a complaint against the hospital.¹⁸

Targeted Infection Control Surveys

On March 4, 2020, as part of a series of actions aimed at limiting the spread of COVID-19, CMS directed State survey agencies to reprioritize survey work to primarily focus on the most serious complaints, including complaints related to infection control.¹⁹ On March 23, 2020, CMS issued a memorandum to State survey agencies indicating that only complaint and special targeted infection control surveys would be conducted over a 3-week period ending April 13, 2020.²⁰ CMS did not set an end date for targeted infection control surveys and they continued after April 13, 2020. The targeted infection control surveys were to use a survey tool provided by CMS to ensure that providers implemented actions to protect the health and safety of individuals in response to COVID-19. CMS directed State survey agencies to resume normal prioritization of surveys on August 17, 2020, but to continue targeted infection control surveys.²¹ State survey agencies performed targeted infection control surveys at certified hospitals and at accredited hospitals over which they had jurisdiction because a sufficiently serious complaint had been filed from March 2020 through the present.

¹⁶ The Act § 1864(c); 42 CFR § 488.9.

¹⁷ In its annual *Report to Congress*, CMS described these deficiencies as “missed” by the accreditation organization. An average of 43 percent of surveys each year missed one or more deficiency for fiscal years 2014 through 2018.

¹⁸ These State survey agency complaint and validation surveys are in addition to the accreditation organizations’ triennial reaccreditation surveys.

¹⁹ CMS Memorandum to State Survey Agency Directors QSO-20-12-All (Mar. 4, 2020).

²⁰ CMS Memorandum to State Survey Agency Directors QSO-20-20-All (Mar. 23, 2020). CMS directed State survey agencies to select hospitals through collaboration with the Centers for Disease Control and Prevention and the Department of Health and Human Services, Assistant Secretary for Preparedness and Response. In addition to performing targeted infection control surveys at certified hospitals, if a State survey agency obtained jurisdiction over an accredited hospital through a sufficiently serious complaint, the State survey agency could perform a special survey such as a targeted infection control survey at the accredited hospital.

²¹ CMS Memorandum to State Survey Agency Directors QSO-20-35-All (Aug. 17, 2020).

Although it could not require accreditation organizations to do so, CMS requested that they also perform targeted infection control surveys at the nearly 4,200 accredited hospitals throughout the country; however, as of January 2021, none were performed. Some accreditation organizations said that they told CMS that they would not perform these surveys because it was not safe to perform them. The organizations also said that, during this period when they believed it was not safe to perform targeted infection control surveys, they performed triennial reaccreditation surveys using remote access technology and placed additional emphasis on infection control.²² During the period for which CMS directed State survey agencies to reprioritize surveys (March 4 through August 17, 2020), accreditation organizations performed 148 triennial surveys and no complaint surveys involving infection control or emergency preparedness.

Other CMS Controls Related to Emerging Infectious Diseases

In addition to its survey, certification, and accreditation controls, prior to 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, including referring providers to information and technical assistance resources provided by the Department of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response's Technical Resources, Assistance Center, and Information Exchange (ASPR TRACIE);
- teleconferences and conference speaking engagements to communicate information or address provider questions; and
- training through CMS's Quality, Safety & Education Portal.

After the Secretary of HHS declared a public health emergency on January 31, 2020,²³ because of the emerging infectious disease COVID-19, CMS promptly:

²² For example, one accreditation organization said that they mounted a camera on a stand and had someone wheel the stand around the hospital.

²³ *Determination That a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus* (Jan. 31, 2020), most recently renewed effective Jan. 7, 2021. Available online at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> and <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx>. Accessed on Mar. 5, 2021.

- issued additional guidance, including referring providers to Centers for Disease Control and Prevention (CDC) guidance;²⁴
- provided regulatory flexibilities to temporarily allow providers not to follow certain rules, such as certain requirements for telehealth services;²⁵
- hosted frequent teleconferences for providers and accreditation organizations to provide information and respond to questions; and
- directed State survey agencies to reprioritize survey work and perform targeted infection control surveys of certified hospitals.²⁶

HOW WE CONDUCTED THIS AUDIT

We identified CMS's control objective, which is to ensure that hospitals maintain quality and safety and respond to risks during an emerging infectious disease outbreak. We then assessed whether CMS's related control activities were designed and implemented to achieve this objective for the approximately 500 hospitals certified to participate in Medicare and Medicaid by State survey agencies and the approximately 4,200 accredited hospitals deemed to be certified. Our audit focused on the design and implementation of those control activities.

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.

²⁴ See, e.g., Memoranda to State Survey Agency Directors QSO-20-09-All (Feb. 6, 2020); QSO-20-13-Hospitals (Mar. 4, 2020).

²⁵ COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. Available online at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>. Accessed on Mar. 5, 2021. The waiver authority is provided when both the Secretary declares a public health emergency and the President declares a major disaster or national emergency. The President declared a national emergency on Mar. 13, 2020. Available online at <https://www.whitehouse.gov/presidential-actions>. Accessed on Mar. 5, 2021.

²⁶ CMS Memoranda to State Survey Agency Directors QSO-20-12-All (Mar. 4, 2020) (reprioritizing surveys only); QSO-20-20-All (Mar. 23, 2020); QSO-20-35-All (Aug. 17, 2020).

FINDINGS

CMS'S CONTROLS WERE WELL-DESIGNED AND IMPLEMENTED BUT ITS AUTHORITY IS NOT SUFFICIENT FOR IT TO ENSURE PREPAREDNESS AT ACCREDITED HOSPITALS

CMS's controls were well-designed and implemented to achieve its control objective and respond to risks, but CMS's authority is not sufficient for it to ensure preparedness for emerging infectious diseases such as COVID-19 at the 4,200 accredited hospitals. The Green Book requires that management design control activities to achieve objectives and respond to risks.²⁷

To meet its objective of ensuring that hospitals maintain quality and safety and respond to risks during an emerging infectious disease outbreak, CMS developed the Emergency Preparedness Rule and related guidance, used its existing survey system to identify noncompliance with the Emergency Preparedness Rule and require corrective action, and responded to infection control risk when COVID-19 emerged in the United States. Further, CMS referred hospitals to advice from ASPR TRACIE and CDC.²⁸ Finally, CMS provided training opportunities and engaged in a communications campaign both before and after the emergence of COVID-19.

These measures were commendable; however, they were not sufficient for CMS to achieve its control objective of ensuring that hospitals maintain quality and safety and respond to risks during an emerging infectious disease outbreak at accredited hospitals. CMS added "emerging infectious diseases" to the definition of the all-hazards approach on February 1, 2019. Because hospitals were not expected to add emerging infectious disease to their plan until their next annual update, not all hospitals would have updated their plans until February 1, 2020. Further, because accreditation organizations are only required to perform reaccreditation surveys every 3 years, CMS cannot determine whether all 4,200 accredited hospitals updated their emergency preparedness plans to include emerging infectious diseases until February 1, 2022.

Additionally, when COVID-19 emerged in the United States, CMS could not evaluate current infection control compliance at the nearly 4,200 accredited hospitals to determine if they were prepared to safely handle a surge of infectious patients. Although CMS requested accreditation organizations to perform COVID-19 related targeted infection control surveys, the accreditation organizations did not perform any as of January 2021. Some accreditation organizations said that it was unsafe to perform these special surveys and only performed triennial "virtual" accreditation surveys through remote technology, though they said they placed an additional emphasis on infection control. During the period when CMS directed State survey agencies to reprioritize surveys (March 4 through August 17, 2020), accreditation organizations performed

²⁷ Green Book, "Control Activities," "Principal – 10 Design Control Activities," § 10.01.

²⁸ See, e.g., [ASPR TRACIE resources web page](#), and [CDC Infection Control Guidance for Healthcare Professionals about Coronavirus \(COVID-19\) resources web page](#). Accessed Mar. 23, 2021.

148 triennial surveys and no complaint surveys involving infection control or emergency preparedness.

CMS's authority over State survey agencies mitigated to some extent the effect of accreditation organizations' not performing targeted infection control surveys. From March 25 through August 17, 2020, State survey agencies performed targeted infection control surveys at 548 accredited hospitals.²⁹ However, this number represents only about 13 percent of the approximately 4,200 accredited hospitals. Moreover, no targeted infection control surveys were performed in 13 States during this period.³⁰

Because CMS has limited authority over accreditation organizations, it could not achieve its control objective of ensuring that accredited hospitals maintain quality and safety and respond to risks during the COVID-19 emergency. Moreover, CMS's limited authority creates a significant risk that it will not be able to ensure quality and safety at the nearly 4,200 accredited hospitals throughout the United States the next time an emerging infectious disease threatens the country.

RECOMMENDATION

We recommend that the Centers for Medicare & Medicaid Services make regulatory changes to allow it to require accreditation organizations to perform special surveys of hospitals selected by CMS:

- after it issues new substantive participation requirements or guidance that it determines warrant additional validation to ensure timely compliance and
- during a public health emergency to address the risks presented by the emergency.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendation. CMS also indicated that, in March 2021, it updated its *State Operations Manual* to include additional planning considerations and preparedness guidance that expanded on emerging infectious diseases. CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding technical comments, are included as Appendix B.

²⁹ As of Mar. 2, 2021, CMS data indicate that State survey agencies had performed targeted infection control surveys at 982 accredited hospitals.

³⁰ Specifically, no targeted infection control surveys were performed in Alabama, Alaska, Delaware, Georgia, Massachusetts, Montana, New Hampshire, New Mexico, Oregon, Pennsylvania, South Dakota, Vermont, and Wyoming. As of March 2, 2021, CMS data indicated that no targeted infection control surveys had been performed in seven of these States.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We identified CMS's control objective and then assessed whether CMS's controls were designed and implemented to achieve its objective regarding the approximately 500 hospitals certified to participate in Medicare and Medicaid by State survey agencies and the approximately 4,200 accredited hospitals deemed to be certified. We limited the scope of our audit to the design and implementation of CMS's controls

We established reasonable assurance by assessing the data for accuracy and completeness as applicable to our audit of CMS's design and implementation controls.

We conducted our audit from April 2020 through April 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal regulations and Federal Register notices;
- reviewed CMS guidance, correspondence, policies, accreditation documents, survey data, and training; and accreditation organizations' policies, survey tools, and reports;
- provided written questions, reviewed responses, and conducted interviews with CMS and the four accreditation organizations to identify and assess the design and implementation of CMS's internal controls;
- reviewed the Green Book components and principles to determine their significance to our audit objective;
- assessed and documented the design and implementation of CMS's internal controls to the extent necessary to address the audit objective; and
- discussed the results of our audit with CMS.

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 B: CMS COMMENTS




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

Date: June 2, 2021

To: Amy J. Frontz
Deputy Inspector General for Audit Services

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

Subject: Office of Inspector General Draft Report: 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)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report. CMS takes seriously its role in emergency preparedness planning.

Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to receive Medicare payments. The CoPs cover a wide array of topics, including an emergency preparedness requirement that directs hospitals to implement an all-hazards approach, which is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the provider and considers the particular type of hazards most likely to occur in their areas. Hospitals are required to review and update their emergency preparedness plan at least biennially.

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 publically available surveyor training that is also used by providers titled, *Universal Infection Prevention and Control*. 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 – 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. On March 26, 2021, CMS further updated Appendix Z to include additional planning considerations and preparedness guidance which expanded on emerging infectious diseases.

As part of CMS's efforts to oversee hospital compliance with Federal requirements, CMS works in partnership with State Survey Agencies (SSAs) and Accrediting Organizations (AOs) to conduct onsite hospital surveys. These surveys are accomplished through observations, interviews, and document/record reviews. SSAs are also authorized by CMS to conduct complaint investigations at hospitals, including those deemed by AOs, when substantial allegations of non-compliance with CoPs are received.

While CMS has oversight responsibilities related to AOs, CMS does not have the same legal relationship with AOs as with SSAs and cannot direct AO surveys in the same manner. CMS is able to direct the SSAs to conduct surveys by statutory authority at Section 1864(a) of the Act, which permits the Secretary to use State health agencies or other appropriate agencies when determining whether health care entities meet Federal standards. By contrast, CMS approves AOs under the authority of section 1865(a) of the Social Security Act (Act), which requires the Secretary to consider factors such as an AO's survey procedures and requirements for accreditation in determining whether to approve an AO. AOs are required by our regulations at 42 CFR 488.5 to have comparable survey processes and standards that either meet or exceed those of CMS, as well as meet other specified requirements. The regulations do not require the AO to perform special surveys at the direction of CMS, such as an infection control survey.

In response to the public health emergency (PHE), CMS issued guidance suspending non-emergency inspections across the country, in order to both contain and limit the spread of COVID-19, and to direct surveyors to turn their focus to the most serious health and safety matters, including targeted infection control surveys. The criteria evolved throughout the course of the PHE to ensure that hospitals implemented the most recent infection control guidance from both CMS and the CDC. This guidance is applicable to any hospital regardless of whether it is certified by the SSAs or is deemed by an AO. As mentioned above, while CMS required SSAs to perform targeted infection control surveys, CMS could only request and encourage AOs to follow the same survey guidance provided to the SSAs. However, during this time, SSAs continued to conduct complaint investigations at deemed hospitals, and if during the course of the complaint survey, non-compliance with a condition such as an infection control requirements was found, that hospital would be cited and would need to correct the deficiency. Furthermore, since CMS has reinstated non-emergency surveys, AOs have begun routine surveys at deemed hospitals.

CMS thanks the OIG for its efforts on this issue and looks forward to working collaboratively on this and other issues in the future. As the work above shows, and as OIG stated, CMS's controls are well-designed and implemented. OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should make regulatory changes to allow it to require accreditation organizations to perform special surveys of hospitals selected by CMS:

- after it issues new substantive participation requirements or guidance that it determines warrant additional validation to ensure timely compliance; and

- during a public health emergency to address the risks presented by the emergency.

CMS Response

CMS concurs with making regulatory changes to require AOs to perform special surveys of hospitals based on CMS's discretion. As OIG acknowledged, CMS's authority over SSAs, and their ability to conduct complaint surveys, mitigated the extent of the effect of AOs not performing targeted infection control surveys.