CMS Pandemic Plan
v. 3.1 Public Release

Effective Date: 01/11/2021

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

This Page Intentionally Left Blank.

Table of Contents

Table of Contents 2
1. Introduction, Purpose, and Objectives 5
1.1 Introduction 5
1.1.1 Scope 5
1.2 Purpose 5
1.3 Objectives 5
2 Context and Assumptions 7
3 Concept of Operations (CONOPs) 8
3.1 Situation Overview: CDC and CMS Pandemic Phases 9
3.2 National Incident Management System 11
3.3 Plans and Procedures 12
4 Policy Response 13
4.1 Areas of Policy Action 13
4.2 Issuance of Waivers and Flexibilities 14
4.2.1 Summary of Waivers and Flexibilities Available To CMS 14
4.2.2 Relevant Categories of Waivers and Flexibilities 18
4.2.3 Waiver and Flexibility Review, and the Approval Waiver and Flexibility Review and Approval Process 22
4.3 Other Areas of Policy Action 26
4.3.1 Clinical Standards and Quality Initiatives 26
4.3.2 Caring For Vulnerable Populations 29
4.3.3 Provider, Program Integrity, Supplier, and Beneficiary Enrollment and Eligibility Policy 31
4.3.4 Program Integrity and Evaluation 32
4.3.5 Value-Based Payment Policies (Including Quality and Financial Measurement and Performance) 33
4.3.6 Accelerated and Advance Payment Programs 33
4.4 Supporting Policy Activities 34
4.4.1 (Section Intentionally Removed) 34
4.4.2 (Section Intentionally Removed) 34
4.5 Reconstitution Activities To Assess Approved Waivers and Flexibilities 34
5 Engagement of External Stakeholders 35
5.1 Scope of Stakeholder Engagement 35
5.2 Forums for Stakeholder Engagement 35
5.3 Rapid Response Correspondence Process 38

5.4 Inquiry Response and Help Desk 39
5.5 Internal Tracking of Stakeholder Concerns 40
5.6 External Scan of Stakeholder Reactions 41
6 Operational Response 42
6.1 Areas of Operational Response 42
7 Direction, Control, and Coordination 46
7.1 Response Governance Structure and Administration 46
7.2 Pandemic Response Team 47
8 Information Sharing and Scenario Planning 51
9 Offices and Centers' Actions By Pandemic Phase 54
9.1 Readiness and Preparedness (Phase 1B) 54
9.2 Pre-Activation (Phase 1C) 56
9.3 Activation (Phase 2A) 60
9.4 Operations (Phases 2B – 2C) 64
9.5 Reconstitution 66
10 Plan Development and Maintenance 69
ANNEX A – Acronyms and Abbreviations 70
ANNEX B – Definitions 72
ANNEX K – Strategic Planning Framework for the Center for Medicaid and CHIP Services 74
ANNEX L – Revision History 88
ANNEX M – Approvals 90

Executive Summary

The COVID-19 pandemic has affected people and industries across the country, exacting a heavy toll on every American. The lives lost and the impact of the economic toll have touched every aspect of American life. With that knowledge and the response experience gained in 2020, CMS improved its Pandemic Plan to ensure the Agency is able to meet the needs of its stakeholders and as a result, now stands better prepared for any future pandemic events. CMS' Pandemic plan has not simply been updated; it has been completely redesigned and provides CMS with the guidance and decision-making framework needed to best meet the needs of its internal and external stakeholders. This plan also details the steps taken to protect those on the CMS workforce who worked tirelessly to fulfill the agency's mission in service to all Medicare and Medicaid beneficiaries and all Americans enrolled in individual or group market coverage.

Readers should pay particularly close attention to **Section 4: Policy Response**, which details the utilization of available waivers and flexibilities, and comprehensively inventories the processes and activities that take place during a pandemic response. In addition, **Section 6: Operational Response** defines a response structure that brings the operational and policy components together, expediting decision-making and accomplishing the goals of the Agency's response.

This revised CMS Pandemic Plan reflects and accounts for the complex and tightly coupled systems in which CMS operations and policy decisions are made. Decisions, data, processes, partner engagements, and key actions were captured to reflect the nimbleness needed to successfully respond to the ongoing Pandemic and to ensure guidance is available for future public health emergencies. This plan is more actionable and applicable to CMS's entire body of work. It is an organized compilation of operational plans and policy playbooks, and will guide CMS in its preparation, response, and recovery from current and future pandemic threats.

1. Introduction, Purpose, and Objectives

1.1 Introduction

The past two decades have proven that novel (new) viral pathogens and subsequent disease, such as Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), Zika, Influenza (e.g., H1N1), Coronavirus Disease 2019 (COVID-19), and even a re-emergence of Ebola virus disease, pose a significant threat to a human population which may not have been previously exposed to these pathogens. Pandemic place an immense stress on government agencies, and specifically, regulatory agencies, which must rapidly institute policy actions to contend with the threat while experiencing significant disruptions to the organization's operations. For the U.S. Department of Health and Human Services (HHS) and its Operational Divisions, this scenario presents a uniquely critical challenge given the HHS's mission of leading the nation in preparing, mitigating, responding to, and recovering from public health and medical emergencies. The Centers for Medicare & Medicaid Services (CMS) are uniquely situated in such a scenario, as CMS must operate at the peak of its capacity as a regulatory and policy-making organization while also sustaining mission essential functions. To succeed in this mission, CMS must thoroughly prepare to withstand the threat of a pandemic from a novel virus.

1.1.1 Scope

This document is concerned with CMS actions to prepare for, respond to, and recover from a pandemic event. Longer-term preparedness actions (e.g.,, amending Standard Operating Procedures (SOPs) in response to past pandemic events) are not covered in this document.

1.2 Purpose

In conjunction with the *CMS Continuity of Operations Plan* (COOP Plan), this Pandemic Plan represents policies and actions that are specific to novel virus pandemics. The procedures outlined in this Plan can also be extrapolated, where appropriate, for other highly contagious pathogens or biological events. This Plan:

- Serves as a tool and reference guide in communicating CMS pandemic preparedness, pandemic response, illness mitigation, and recovery strategy.
- Assists CMS leadership in decision-making before, during, and after a pandemic.
- Ensures compliance with CMS, HHS, Federal Emergency Management Agency (FEMA), and Federal regulations, guidance, and directives.
- Adheres to Department of Homeland Security (DHS) and White House continuity planning mandates and directives.

1.3 Objectives

The objectives of this plan include:

- Protect the health and safety of CMS personnel, vendors and visitors by providing guiding principles for illness mitigation and recovery during a pandemic.
- Identify the roles and responsibilities of CMS in participating in a whole-of-government response.
- Capture important policy and operational decision-making criteria to facilitate rapid implementation of waivers and flexibilities.
- Ensure that CMS can maintain its Mission-Essential Functions (MEFs) and Essential Supporting Activities (ESAs) in the face of significant and sustained disruptions to its operations and workforce.
- Ensure the continuity of CMS leadership.
- Communicate pandemic preparedness before, during, and in the aftermath of a pandemic to all stakeholders.
- Achieve timely and orderly recovery for CMS from a pandemic, resuming all functions and services while maintaining readiness and preparing for potential additional waves of illness.
- Outline the steps the agency should take in the event of a Pandemic.

2 Context and Assumptions

Pandemics are extremely unpredictable. Using basic assumptions provided by the World Health Organization (WHO), CMS could expect that a novel virus pandemic could begin at any time of the year, in any place in the world, and could spread across the globe within several weeks or months. Medicare, Medicaid, and Children's Health Insurance Programs (CHIP) beneficiaries, and enrollees in health coverage, such as through a Health Insurance Marketplace®[1] may encounter significant interruptions and delays in medical care as in-person provider consultations are halted or significantly modified due to infectious disease risk. Individuals may also encounter significant interruptions and delays in eligibility and enrollment processes for these programs. CMS' workforce may also experience absenteeism exceeding the actual clinical attack rate for the particular pandemic. The pandemic planning efforts are based upon several critical assumptions:

- CMS will receive pandemic updates and follow directives from HHS, Office of the Assistant Secretary for Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), FEMA, Occupational Safety and Health Administration (OSHA), the General Services Administration (GSA), and the White House.
- CMS will follow local emergency management and public health directives.
- CMS will work collaboratively with all HHS components and other Federal, State, Local, Tribal, and Territorial (FSLTT) agencies to enact an effective response.
- CMS employees, Vendor Partners, and visitors are responsible for adhering to personal infection control and prevention procedures.

Additionally, pandemic planning efforts are based on the context around what CMS may expect to happen within a pandemic scenario:

- There will be considerable uncertainty surrounding the extent of the outbreak within the initial reporting country. The science and understanding of the virus and viral dynamics (i.e., replication, transmissibility, infectivity rate, etc.) as well as the clinical spectrum of the disease and containment measures will rapidly evolve, necessitating regular updates to the planning assumptions as gaps in our knowledge of the disease are filled.
- Human-to-human transmission may be amplified in specific settings, including healthcare and nursing home facilities. Community transmission is also likely to be widespread within the initial reporting country.
- While the response will emphasize rapidly preventing infection transmission, (e.g., identifying, isolating), and treating imported cases, there is likely to be a risk of clusters of cases caused by localized community transmission.
- Isolation and quarantine protocols may be put in place to slow and prevent the spread of infection.

[1] Health Insurance Marketplace is a registered service mark of HHS.

3 Concept of Operations (CONOPs)

CMS' pandemic operations fit within the overall federal response environment that includes the CDC, FEMA, and the other HHS Operating Divisions. CMS operates in concert with these agencies by following a corresponding timeline and by standing-up internal governance structures.

Specifically, CMS concept of operations (CONOPS) actions follow five distinct phases that closely correspond to FEMA's Operational Phases and the CDC Intervals, discussed in Section 3.1. The five CMS Phases are: (1) Readiness and Preparedness, (2) Pre-activation, (3) Activation, (4) Operations, and (5) Reconstitution. Figure 1 shows how the FEMA Phase numbers and phase titles, CDC Intervals, and CMS Pandemic Plan Phases relate to each other. CDC intervals are delineated by particular triggers that are discussed in more detail in Section 3.1.

PHASE NUMBER	1B	1C	2A	2B	2C		
FEMA OPERATIONAL PHASE	Increased Likelihood or Elevated Threat	Near Certainty or Credible Threat	Activation, Situational Assessment, and Movement	Employment of Resources and Stabilization	Intermediate Operations		
CDC INTERVAL	Investigation	Recognition	Initiation	Acceleration		Deceleration	Preparation
CMS PANDEMIC PLAN	Readiness and Preparedness	Pre-Activation	Activation	Operations		Reconstitution	
TRIGGER	Identification of a confirmed human case of a novel or re- emerging virus infection anywhere with potential to cause significant human disease and potential for pandemic.	Confirmation of multiple human cases or clusters with virus characteristics indicating limited human-to-human transmission and heightened potential for pandemic. Determination of a significant potential for a public health emergency.	Demonstration of efficient and sustained human- to- human transmission of the virus. Declaration of a Public Health Emergency (PHE). Sustained human to human transmission (3rd generation) and exportation of cases without China nexus	Increasing number of cases or increasing rate of infection in U.S. Healthcare system burden exceeds State resource capabilities. State/local request for assistance that requires federal coordination. More than 3 generations of human-to-human transmission in multiple noncontiguous U.S. locations Evidence that public health systems in multiple U.S. locations are unable to meet the demands of achieving containment efforts or providing care	Increasing rate of infection in U.S. indicating established transmission, with long-term service disruption and critical infrastructure impacts. Presidential Stafford Act declaration. State/local request for assistance that requires federal coordination.	Consistently decreasing rate of pandemic virus cases in the United States.	Low pandemic activity but continued outbreaks possible in some jurisdictions.

Figure 1: Phase Indicators and Triggers (FEMA, 2018)[2]

[2] The FEMA plan aligns the federal operational response phases outlined in the Response Federal Interagency Operational Plan and the Biological Incident Annex with the CDC intervals, which are outlined in the Pandemic Intervals Framework, as well as identifying triggers that move action between the phases, and organizes the interagency response activities to the phases.

3.1 Situation Overview: CDC and CMS Pandemic Phases

The CDC published its Updated Preparedness and Response Framework for Influenza Pandemics (2014) wherein it outlined its efforts to construct a common framework from which CDC and other FSLTT governments and agencies can plan and coordinate their actions. It is assumed the same framework would be used during a novel virus outbreak. This approach defines six specific intervals and triggers for action as illustrated in Figure 2 below. The text below provides the CDC's interval description for reference. Although the phases are presented linearly, due to the rapidly changing nature of a pandemic, the duration of specific phases may be compressed (or even skipped) as triggers for subsequent phases swiftly emerge. Additionally, subsequent waves of an outbreak may necessitate urgent transitions back to early phases.

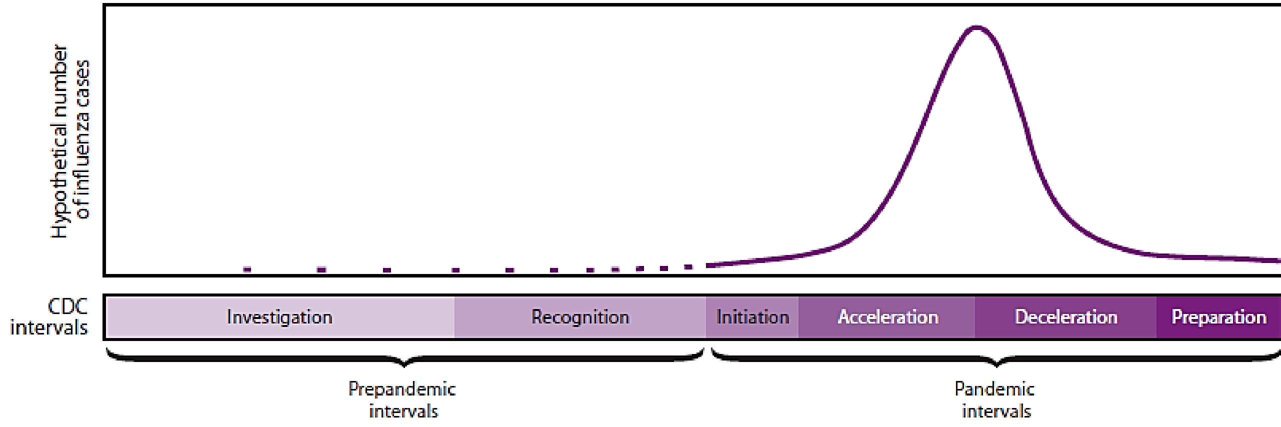


Fig. 2: Preparedness and response framework for novel influenza A virus pandemics: CDC intervals (CDC, 2014)

Investigation Interval

The identification and investigation of a novel viral infection in humans or animals anywhere in the world is judged by subject-matter experts to have potential implications for human health. Public health actions focus on targeted surveillance and epidemiologic investigations to identify human infections and assess the potential for the virus to cause severe disease in humans, including person-to-person transmission, co-investigations of animal outbreaks with animal health representatives, and consideration of case-based control measures (i.e., antiviral treatment and antiviral chemoprophylaxis of contacts for infected humans and isolation of humans and animals who are infected).

Indicators: Identification of novel infection in humans and/or animals anywhere in the world with potential implications for human health.

Recognition Interval

Increasing numbers of human cases or clusters of novel viral infection are identified anywhere in the world, and the virus characteristics indicate an increased potential for ongoing human-to-human transmission. Public health actions concentrate on control of the outbreak, with a focus

on the potential use of case-based control measures, including treatment and prevention of infection transmission (e.g., isolation of ill persons and voluntary quarantine of contacts).

Indicators: Increasing number of human cases or clusters of novel infection anywhere in the world with virus characteristics, indicating increased potential for ongoing human-to-human transmission.

Initiation Interval

The first human cases of a pandemic viral infection are confirmed anywhere in the world with demonstrated efficient and sustained human-to-human transmission. Continued implementation of case-based control measures and routine personal protective measures (e.g., hand hygiene) is essential, as is enhanced surveillance for detecting additional cases of the novel virus to determine when community mitigation measures should be implemented.

Indicators: Confirmation of human cases of a pandemic virus anywhere in the world with demonstrated efficient and sustained human-to-human transmission.

Acceleration Interval

The rate of pandemic cases identified in the United States is consistently increasing. Consideration of immediate initiation of appropriate community mitigation measures, including facility closures and social distancing, is of primary importance. Isolation and treatment of ill persons, contact tracing, and voluntary quarantine of contacts continue as key mitigation measures. Historical analyses and mathematical modeling indicate that early institution of combined, concurrent community mitigation measures might maximize the reduction of disease transmission and subsequent mortality in the affected areas.

Indicators: Consistently increasing rate of pandemic virus cases identified in the United States, indicating established transmission.

Deceleration Interval

When the pandemic case rates in the United States are consistently decreasing. Planning for the suspension of community mitigation measures and recovery can begin. State or local health officials might rescind community mitigation measures in certain regions within their jurisdiction when no new cases are occurring or are occurring infrequently.

Indicators: Consistently decreasing the rate of pandemic virus cases in the United States.

Preparation Interval

Outbreaks could continue occurring in various jurisdictions, but the interval is characterized by low pandemic activity. The declining activity provides the opportunity to focus on discontinuing community mitigation measures; facilitating the recovery of the public health, healthcare, and community infrastructure; resuming enhanced surveillance protocols to detect subsequent waves; evaluating the response to the initial wave; and preparing for potential additional waves of infection.

Indicators: Low pandemic activity but continued outbreaks possible in some jurisdictions.

3.2 National Incident Management System

(1) There are two mechanisms by which a national emergency may be declared, the Stafford Act and the National Emergencies Act both authorize the President to declare a state of emergency to activate federal government agencies to provide assistance and funding for a wide range of emergency response activities.

(2) Under Section 319 of the Public Health Service Act, the Secretary of Health and Human Services (HHS) may declare a public health emergency (PHE) after determining a disease or disorder presents a significant threat to the nation's health. Unless the Stafford Act or National Emergencies Act are also used, limited powers are triggered under a Section 319 declaration.

Given the potential geographically distributed nature of a pandemic, strong coordination among federal agencies and with states, tribes, territories, and local leaders is critical to successfully manage a pandemic. The National Incident Management System (NIMS) provides a systematic approach to emergency management that guides the federal government's response. NIMS outlines scalable, flexible, and adaptable concepts that are codified in the updated National Response Framework (NRF), Fourth Edition released in October 2019.[3] Executive branch decision-making is centered in the White House, which has historically launched a taskforce consisting of senior officials from relevant federal agencies to address pandemic emergencies. In prior PHEs, the Secretary of HHS, the ASPR, the Administrator of CMS, and leaders of key national health and emergency response agencies were members of the White House taskforce.

Under the NRF, HHS is designated an Emergency Support Function (ESF) primary agency tasked with ensuring ESF #8 – Public Health and Medical Services for all emergency situations.[4] CMS acts as an ESF support agency with responsibility for providing statutory capabilities and resources to support HHS and CMS' mission-essential functions. To coordinate CMS' response with other federal agencies, CMS will designate federal liaisons to provide support and information transfer between CMS and other federal agencies leading the nation's pandemic response.

The responsibilities of key federal health agencies in the nation's pandemic response are detailed below:

- The **Centers for Disease Control and Prevention** are principally tasked with monitoring the public health impact of the disease, providing guidance to public health departments, healthcare facilities, the general public, and coordinating scientific investigation of the novel pathogen. The CDC also employs epidemiological modeling to identify and forecast outbreaks.

[3] See National Response Framework.

[4] See page 40 of National Response Framework. See HHS Concept of Operations for ESF #8.

- The **Centers for Medicare & Medicaid Services** employ regulatory policy to ensure Medicare, Medicaid, and CHIP beneficiaries can receive continuous access to quality healthcare and provide timely payment of claims to support healthcare providers' economic stability.
- The **Federal Emergency Management Agency** acts to support local, state, and federal government officials' emergency operations, including assistance establishing temporary and alternate care clinics and facilities, acquisition of Personal Protective Equipment (PPE) and supplies, and in enhancing general emergency preparedness.
- The **Assistant Secretary for Preparedness and Response (ASPR)** within HHS acts to lead the nation's medical and public health preparedness for disasters and public health emergencies. ASPR has the authority to deploy federal public health and medical personnel (including the National Disaster Medical System), supports the deployment of the U.S. Public Health Service Commissioned Corps and acts to coordinate with federal health officials to ensure integration of federal preparedness and response activities during emergencies.

3.3 Plans and Procedures

A severe pandemic threat may require initiation of CMS' Continuity of Operations Plan (COOP) and other contingency operations. After the CDC identifies a viral infection with pandemic potential, all components should review, consult, and adapt relevant emergency plans and procedures, including:

- Pandemic Plan
- COOP Plan/Devolution Plan
- Mission Essential Functions (MEFs)/Essential Supporting Activities (ESA)
- Emergency Relocation Group (ERG)/Devolution Emergency Response Group (DERG) Rosters
- Orders of Succession/Delegations of Authority
- Essential Records
- Standard Operating Procedures

Activation of the pandemic plan as ordered by the President, the Secretary of HHS, or by the CMS Administrator or their designees will trigger actions delineated in the plans above. For example, activation of the pandemic plan requires the CMS Continuity of Operations team to implement the steps of Phase I: Readiness and Preparedness in the CMS COOP Plan, which readies the organization to monitor and prepare for any changes in CMS' ability to perform its mission essential functions. Similarly, components will be required to report the status and prioritization of their business functions in accordance with their respective Business Continuity Plans.

4 Policy Response

CMS may enact waivers and flexibilities to support states, providers, beneficiaries, and external stakeholders impacted by the pandemic emergency. The following subsections detail critical areas of action and necessary processes to enable CMS to respond quickly and effectively to pandemic events. Across Components, the Policy Group (see Section 7 for additional information on the response governance structure) will lead CMS' response and may create a sub-team (referenced herein as the Waiver Work Group) to provide targeted input on waivers and flexibilities approved in response to the pandemic. Additional details on waivers and flexibilities issued in prior pandemics and component responsibilities in executing the policy actions described below can be found at Coronavirus waivers & flexibilities.

4.1 Areas of Policy Action

In responding to the pandemic, CMS may take action across several primary areas to support states, providers, and external stakeholders in ensuring continued access to quality care for beneficiaries during a pandemic. Subsequent sections below will address each of the following topics, which may be applicable to CMS' policy response:

- Issuance of waivers and flexibilities to enable providers to continue to offer covered health services under adverse circumstances in response to the public health emergency. Such waivers and flexibilities might address issues concerning:
    - Telehealth and other remote services (including with respect to mental and behavioral health services)
    - Hospital capacity
    - Healthcare workforce
    - Testing
    - Reducing administrative burden (including clinical standards and quality initiatives, audit activities, data reporting for quality assessment and measures, Innovation Center model timelines and data reporting, cost reporting extensions, physical environment and equipment maintenance, isolation and grouping together of patients, etc.).
    - State relief and flexibilities.
    - Waiver and flexibility approval processes.
- Issuance of waivers and flexibilities to state Medicaid and CHIP in response to the public health emergency.
- Other areas of policy action:
    - Caring for vulnerable populations, including technical assistance and published resources.
    - Provider, supplier, and beneficiary enrollment and eligibility policy.
    - Value-based payment programs (including quality and financial measurement and performance).
    - Accelerated and Advance Payment programs.

- Issuance of flexibilities and relaxed enforcement for health insurance issuers offering group or individual health insurance coverage to remove barriers and allow issuers to respond to an emergency and provide their enrollees with necessary coverage and services.
- Supporting policy activities:
  - Issuance of policy documents, guidance, and press releases, including clearance processes.
  - Non-CMS policy response and approval process.
  - Program integrity activities.

Actions that may be taken across each of these areas to respond to a pandemic are detailed below, including internal CMS processes and tools to support the execution of each. Additional supporting information on the execution of the processes detailed below can be found at Coronavirus waivers & flexibilities.

4.2 Issuance of Waivers and Flexibilities

If the President declares a state of emergency under the Stafford Act or National Emergencies Act, and the HHS Secretary declares a PHE in the affected area, CMS is empowered to temporarily modify or waive certain Medicare, Medicaid, and CHIP requirements (described at Section 1135(b) and 1812(f) of the Social Security Act) as determined necessary by the Agency.

4.2.1 Summary of Waivers and Flexibilities Available To CMS

Medicare Waivers

Formal Waivers

There are two types of formal Medicare waivers that can be blanket or specific:

1) Section 1135(b) Waivers (“1135 waivers”)
   - Formal waivers specified in Section 1135(b) of the Social Security Act (1135 waivers) may temporarily waive or modify certain Medicare requirements to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods and that providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).
   - 1135 waivers end no later than the termination of the emergency period (including extensions) OR 60 days from the date the waiver or modification is first published, whichever is later.

1135 Waivers do not offer grants or financial assistance, do not pay for services that are not usually covered, and do not provide eligibility for Medicare to people who are not otherwise eligible.

Section 1135(b) of the Social Security Act authorizes CMS to waive requirements in the following areas:

- Conditions of participation or other certification requirements applicable to providers and suppliers.
- Program participation and similar requirements.
- Preapproval requirements.
- Licensure requirements applicable to physicians and other health professionals.
- Sanctions for violations of certain emergency medical requirements under the Emergency Medical Treatment and Labor Act (EMTALA Section 1867(a) waivers).
- Sanctions for violations of the Physician Self-Referral Law (Stark Law 1877(g) Waivers).
- Performance deadlines and timetables (modifiable only; not waivable).
- Certain payment rules regarding Medicare telehealth services, including geographic and setting of care requirements.

Source: 1135 Waiver- At A Glance

2) Title XVIII Section 1812(f) Waivers
   - Section 1812(f) of the Social Security Act authorizes the HHS Secretary to provide for Skilled Nursing Facility (SNF) coverage in the absence of a qualifying 3-day prior inpatient hospital stay ("3-day qualifying hospital stay") provided this action does not increase overall program payments and does not alter the SNF benefit's acute care nature.

Non-1135 Waivers ("Informal Waivers")

An "informal waiver" is a discretionary waiver or relaxation of procedural guidance when such norm is not required by statute or regulation, but rather is reflected in CMS sub-regulatory guidance or policy. These procedures may be waived or relaxed administratively if circumstances warrant.

State Medicaid and CHIP Waivers

In a PHE, state Medicaid and CHIP agencies may request waivers and flexibilities from CMS through the following primary authorities:

- **Section 1135 Waivers**
  State-requested 1135 waiver relief and flexibilities for Medicaid and CHIP programs. CMS may also provide a blanket waiver without specific requests from states.

- **Section 1115 Demonstrations**
  Section 1115 of the Social Security Act gives HHS the authority to approve experimental, pilot, or demonstration projects found by the Department to be likely to assist in promoting the objectives of the Medicaid program. This authority can be used to support state-led innovations in care provision.

- **Home and Community-Based Services Section 1915(c) Appendix K Amendments**
  Appendix K amendment requests allow states to amend previously approved 1915(c) waivers. These waivers accelerate changes to home and community-based services or provide emergency amendments.

- **Medicaid Disaster State Plan Amendments**
  The Medicaid state plan describes the state's rules related to eligibility, benefits, and payments; states have wide discretion to design their programs within federal parameters, and changes are processed through state plan amendments. During a disaster or emergency, states may make certain temporary changes.
- **CHIP Disaster State Plan Amendments**
  Similar to Medicaid Disaster State Plan Amendments, states and territories may wish to make temporary changes to their CHIP programs in an emergency.
- **Emergency Requests for IT Funding**
  Existing regulatory authority allows states to make emergency requests for IT funding.
- **Regulatory Concurrences**
  Medicaid and CHIP regulations allow states some flexibility during an emergency where they can make temporary adjustments to their existing eligibility and enrollment processes. Although formal approval is not required from CMS, many states document these changes by sending letters or emails to CMS for purposes of "regulatory concurrence" and for audit purposes.

In addition to these primary authorities, CMS also has the regulatory authority to provide states with flexibility in other areas. In the area of Medicaid managed care, CMS can approve states' requests to amend their managed care capitation rates including direct payments made by plans to certain providers.

	Examples from COVID-19 Response
Waiver/Flexibility	**Description of Template or Checklist**
1135 Waiver Checklist	Pre-populated checklist with commonly requested waivers or modifications, including: • Temporarily suspend prior authorization requirements. • Extend existing authorizations for services through the end of the COVID-19 PHE. • Modify certain timeline requirements for state fair hearings and appeals. • Relax provider enrollment requirements to allow states to more quickly enroll out-of-state or other new providers to expand access to care. • Relax public notice and submission deadlines for certain COVID-19 focused Medicaid state plan amendments, enabling states to make changes faster and ensure they can be retroactive to the beginning of the COVID-19 PHE.
1115 Demonstration Opportunity and Checklist	As announced in a State Medicaid Director Letter (SMDL #20-002), states may apply for a section 1115 demonstration related to COVID-19 and seek federal approval of waivers of certain federal rules to streamline enrollment into long-term care programs and home and community-based services, as well as access broad authorities to vary and target services based on population needs. The SMDL included a demonstration checklist to streamline the application process, and no public notice period was required.
1915(c) Appendix K Template	Pre-populated template with commonly requested and relevant program changes to home and community-based services, including: • Temporarily modify access and eligibility to programs. • Temporarily modify services included and location where provided (including addendums to specify services which should be added or modified). • Temporarily modify providers authorized to perform or be compensated for the service.

	Examples from COVID-19 Response
Waiver/Flexibility	**Description of Template or Checklist**
	• Temporarily modify level of care requirements. • Temporarily increase payment rates. • Temporarily modify service plan development processes. • Temporarily modify incident reporting requirements. • Temporarily institute or expand opportunities for self-direction. • Increase Factor C. There is also a general Appendix K template that is broader and can be used by states to tailor their section 1915(c) home and community-based services waivers.
Medicaid Disaster Sate Plan Amendment Template	Template allows for temporary changes to Medicaid programs addressing, for example, the COVID-19 PHE, including: • Expanded temporary coverage for optional eligibility groups. • Add or modify benefits. • Expanded telehealth service delivery. • Temporarily increase provider reimbursement.
Medicaid Managed Care Direct Payment Templates	In response to increased volatility in provider utilization rates, CMS provided several options states may consider under their Medicaid managed care contracts including direct payments to certain providers.

Source: Medicaid.gov

Flexibilities For Health Insurance Issuers Offering Group Or Individual Health Insurance Coverage

The Center for Consumer Information and Insurance Oversight (CCIIO) may provide for relaxed enforcement of certain policies or procedural timeframes in order to remove barriers and provide flexibility to facilitate the nation's response to the public health emergency posed. In particular, CCIIO may provide for these flexibilities to allow issuers to respond to an emergency and provide their enrollees with necessary coverage and services. For example during the COVID-19 PHE, CCIIO provided states and issuers the following flexibilities[5]:

- FAQs on Availability and Usage of Telehealth Services through Private Health Insurance Coverage in Response to Coronavirus Disease 2019 (COVID-19): Issuers in the individual and group markets are generally not permitted to modify a health insurance product mid-year. These FAQs announced that CMS would not take enforcement action against any health insurance issuer in the individual or group market that makes mid-year changes to the health insurance product to provide greater coverage for telehealth services or to reduce or eliminate cost-sharing requirements for telehealth services,

[5] A list of CCIIO COVID-19 FAQs is available online: Coronavirus Disease 2019 (COVID-19) Guidance

even if the specific telehealth services covered by the change are not related to COVID-19.

- Payment and Grace Period Flexibilities Associated with the COVID-19 National Emergency: CMS exercised enforcement discretion to permit issuers of qualified health plans and stand-alone dental plans to extend payment deadlines for initial binder payments as well as ongoing premium payments during the period of the COVID-19 public health emergency.
- Temporary Period of Relaxed Enforcement for Submitting the 2019 Medical Loss Ratio (MLR) Annual Reporting Form and Issuing MLR Rebates in Response to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: CMS exercised discretion to adopt temporary policies of relaxed enforcement to permit issuers to prepay to enrollees a portion or all of the estimated MLR rebate for the 2019 MLR reporting year to support continuity of coverage for enrollees who may struggle to pay premiums because of illness or loss of income resulting from the COVID-19 public health emergency. CMS also extended the deadline by which it will accept 2019 MLR Annual Reporting Forms.
- Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency: CMS announced a temporary policy to allow health insurance issuers in the individual and small group markets to temporarily offer premium credits for 2020 coverage to support continuity of coverage for individuals, families and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19 public health emergency.
- In certain circumstance, the Department of Labor (DOL) and the Department of the Treasury, along with HHS may provide for flexibilities for group health plans and health insurance issuers offering group or individual health insurance coverage. HHS, DOL, and Treasury may also exercise discretion to adopt temporary policies of relaxed enforcement in connection with certain standards affecting this market.

4.2.2 Relevant Categories of Waivers and Flexibilities

CMS has effectively issued multiple waivers and flexibilities during prior emergencies. CMS may issue waivers and flexibilities across six primary categories, which have been used in the COVID-19 response and may be applicable in similar future emergency response efforts. A brief description of each of the six categories is included below; see Coronavirus waivers & flexibilities for a detailed inventory of waivers and flexibilities approved during the COVID-19 pandemic.

- **Telehealth and Other Remote Services:** Waivers and flexibilities to expand the availability of services provided via telehealth or other remote services assist Medicare, Medicaid, and CHIP beneficiaries, and enrollees in health insurance coverage, including coverage through a Health Insurance Marketplace®[6] in continuing to access health services when traditional access (e.g., hospitals, doctors'

[6] Health Insurance Marketplace is a registered service mark of HHS.

offices) may be adversely impacted by pandemic conditions. The use of telehealth will help ensure that individuals are able to receive care from home, which could mitigate the spread of the virus. It could also reduce costs including those associated with PPE since services are being provided remotely. Approved waivers and flexibilities may cover topics including:

- Broadening the scope of services that may be provided via telehealth.
- Allowing additional providers to use telehealth and related definitions and settings.
- Allowing supervision to be done remotely.
- Permitting coverage or payment for telephone-only services.
- Removing frequency limits.
- Removing prior relationship requirements.
- Developing documentation and coding simplifications.
- Allowing telehealth to be furnished without regard to geographic or clinical setting of care (as long as the services are furnished in the U.S.).

Please note that some of these waivers and flexibilities are authorized by statute and are applicable ONLY to the COVID-19 PHE; there would be no statutory authority to apply them to any future PHEs.

HHS, along with the DOL and the Department of Treasury (the Departments), also announced flexibilities for group health plans and issuers of group and individual health insurance to increase coverage for telehealth services and for large employers to offer coverage only for telehealth and other remote care services to employees who are not eligible for any other group health plan offered by the employer under certain circumstances.

The Departments share interpretive jurisdiction over the market reforms enacted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Affordable Care Act, and other consumer protection laws. DOL administers the Employee Retirement Income Security Act and has enforcement jurisdiction over private-sector employment-based group health plans. Under the Internal Revenue Code, Treasury has authority over group health plans (including church plans) and employers, and the Internal Revenue Service enforces the requirements of the Code through the imposition of an excise tax. HHS administers the Public Health Service Act (PHS Act). HHS has direct enforcement authority with respect to non-Federal governmental plans (those sponsored by State and local governments), as well as health insurance issuers in the group and individual markets in states that do not have authority to enforce or fail to substantially enforce applicable PHS Act requirements.

As required by statute (HIPAA section 104), the three agencies operate under a memorandum of understanding, which provides that the shared provisions must be administered so as to have the same effect at all times and the Departments must coordinate to avoid duplication and assign priorities in enforcement efforts.

- **Increase Hospital Capacity:** Waivers and flexibilities allow hospitals to treat more patients both on-site and at safe alternate locations while proactively preparing the

healthcare system to triage and treat high volumes of patients who may fall ill due to the pandemic. Waivers and flexibilities may include:
  - Expanding or relocating locations where healthcare services can be provided.
  - Allowing Ambulatory Surgical Centers to temporarily enroll in Medicare as hospitals.
  - Allowing temporary increases in hospital bed capacity.
- **Rapidly Expand the Healthcare Workforce:** Removing barriers to rapidly and temporarily expand the healthcare workforce allows clinicians to practice at the top of their license and empowers non-physicians to expand the care they are eligible to provide to patients in need, reducing the burden on the nation's physicians and preparing the healthcare workforce to engage with and treat high volumes of patients affected by the pandemic. Waivers and flexibilities may focus on:
  - Easing supervision requirements.
  - Allowing supervision to be done remotely.
  - Relaxing in-person and visit requirements if not required as a condition of payment.
  - Allowing clinicians to practice at the top of their license.
  - Providing more flexibilities for rural providers.
  - Expanding the available workforce.
- **Testing:** Expanded access to Food and Drug Administration (FDA) approved or cleared screening and diagnostic testing for Medicare and Medicaid beneficiaries, and enrollees in health insurance coverage, including coverage through a Health Insurance Marketplace®[7] assists public health authorities in monitoring and mitigating the spread of a pandemic. Waivers and flexibilities may focus on topics like:
  - Expanding access to testing by providing coverage for testing performed at "parking lot" testing sites or for laboratory processing of self-collected laboratory test systems that the FDA has authorized for home use.
  - Expanding access to testing for Marketplace enrollees at both in and out of network testing sites with no cost sharing
  - Expanding the ability of pharmacies and research laboratories to rapidly contribute to national or local testing.
- **Reducing Administrative Burden:** Additional waivers and flexibilities reduce burden on payers and providers to meet reporting and data requirements while simultaneously providing critical services to beneficiaries by suspending or modifying program requirements. Waivers and flexibilities may focus on:
  - Pausing or modifying certain criteria for CMS programs, including data submission deadlines, application cycles, and cost reporting extensions.
  - Providing temporary relief from or modifications to audit activities.
  - Providing temporary relief from or modifications to data reporting for quality assessment and measures (including Quality Payment Programs).
  - Modifying policies for Innovation Center models, including model timelines, data reporting, and financial methodology calculations.

[7] Health Insurance Marketplace is a registered service mark of HHS.

- Modifying physical environment and equipment maintenance requirements.
- Temporarily waiving or modifying requirements on isolating and grouping together of patients.

- **State Relief and Flexibilities**: As discussed in Section 4.2.1 above, the Centers for Medicaid and CHIP Services (CMCS) may approve waivers, amendments, and flexibilities for US states, including the District of Columbia, and US territories to allow Medicaid and CHIP programs to adapt their operations as necessary to respond to the pandemic. As documented in Section 4.2.1, CMS may approve state requests for flexibilities under the following authorities:
  - Section 1135 Waivers.
  - Medicaid Disaster State Plan Amendments.
  - 1915(c) Appendix K Amendments.
  - CHIP Disaster State Plan Amendments.
  - Section 1115 demonstrations.
  - Emergency requests for IT funding.
  - Regulatory concurrences.
  - Medicaid Managed Care regulations for state directed payments.

NOTE: CMS may utilize rule-making processes to issue Interim Final Rules with Comment Period (IFC) to provide flexibilities that cannot be waived or modified under the authority of section 1135 or 1812 of the Act. In engaging in the rule-making process, CMS will ensure continued collaboration and coordination among Centers providing input into the IFC. Links to IFCs issued in prior pandemics can be found at Current emergencies.

Following resolution of the PHE, the CMS Waiver Work Group will review issued policy actions to identify waivers and flexibilities for termination. The Administrator may review and approve or reject all recommended discretionary policy actions by the working group. See Section 5.4 below for additional details on this review and “unwinding” process.

Reinforcing Flexibilities Via Administrative and Policy Memo

To support and communicate actions taken in coordination with the CDC on topics like survey prioritization and infection control, CMS may amplify newly issued guidance and regulations by releasing administrative or policy memos that clarify and reinforce approved flexibilities, particularly with respect to health and safety standards. CCSQ memos may also augment waivers and flexibilities issued on other pandemic policy topics, including hospital capacity, the healthcare workforce, and administrative burden, among others.

Administrative and policy memos will be centrally housed on CCSQ’s Quality, Safety, and Oversight Group’s page on CMS.gov and should be distributed to providers and beneficiaries through available listservs and stakeholder engagement forums (See Section 5 below). Released memos should be revised and updated as needed as the pandemic event continues; CMS may re-publish applicable memos with red text or otherwise indicating revisions or updates resulting from the release of new waivers, flexibilities, or guidelines.

Examples from COVID-19 Response
During the COVID-19 pandemic, CMS issued over 40 administrative memos to reinforce approved flexibilities. Topics covered in administrative memos included: • Targeted infection control guidance for the following settings of care: o Nursing homes (including visitation restrictions). o End-Stage Renal Disease (ESRD) facilities. o Intermediate care facilities for individuals with intellectual disabilities. o Psychiatric residential facilities. • Guidance for managing COVID-19 cases in the following care settings, including screening, treatment, and transfer to higher level care where needed: o Hospice and Home health. o Religious nonmedical healthcare institutions. o Ambulatory Surgical Centers (ASCs). o Community mental health centers. o Comprehensive Outpatient Rehabilitation Facilities (CORFs). o Outpatient physical therapy or speech pathology service. o Rural health clinics (RHCs). o Federally qualified health centers (FQHCs). • Amplification of CDC guidelines on appropriate use of PPE and general infection control information. • Notification of survey prioritization changes, including protocols for inspecting facilities with suspected or confirmed COVID-19 cases and targeted infection control toolkits and checklists. • Guidance and FAQs for critical access hospitals (CAHs) and hospitals on implications of COVID-19 for compliance with Emergency Medical Treatment and Labor Act (EMTALA), including screening obligations and stabilization, transfer, and recipient hospital obligations. • Guidance to Clinical Laboratory Improvement Amendments (CLIA) laboratories regarding review of pathology slides, proficiency testing, alternate collection devices, and requirements for a CLIA certificate during the PHE (including FAQs), including clarification that CLIA programs are not eligible for 1135 waivers. • Guidance and processes for licensed independent free-standing emergency departments and ASCs submitting attestations and certification kits to CMS Regional Offices to temporarily enroll as hospitals during the COVID-19 PHE. • Guidance for transfers or discharges in long-term care facilities. • Summary of nursing home reporting requirements for COVID-19 related information to the CDC and residents/resident representatives, including information on how to enroll in reporting systems. • Recommendations on reopening nursing homes for state and local officials. • Information concerning EMTALA Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19)

Source: Policy & Memos to States and Regions

4.2.3 Waiver and Flexibility Review, and the Approval Waiver and Flexibility Review and Approval Process

In a pandemic, subject to Presidential and Secretarial declarations, CMS may issue emergency waivers under Section 1135 of the Social Security Act as blanket waivers (implemented for all similarly situated providers in an emergency area) or as individual waivers (specific to and generally requested by a certain provider and determined at the regional office level). In issuing waivers and flexibilities, CMS will consult subject matter experts across the Agency to evaluate how these approvals may impact vulnerable populations. Section 4.3.2 below details

considerations for policy-making specific to vulnerable populations, but CMS will also consider the impact of enterprise-wide policies on these populations.

Medicare Waivers Proactively Issued In Response to Pandemic

Immediately after a pandemic begins (when the President declares a disaster or national emergency and the HHS Secretary declares a PHE), CMS may proactively issue several disaster-related waivers and flexibilities through a blanket waiver. Under Section 1135 or 1812(f) of the Social Security Act, CMS can issue several blanket waivers when there is a disaster or emergency. When a blanket waiver is issued, providers do not have to apply for an individual waiver. Blanket waivers prevent access to care gaps for beneficiaries affected by the emergency. If there is no blanket waiver, providers can ask for an individual Section 1135 waiver by following our instructions.

CMS' Waiver Work Group utilizes the following process to coordinate and issue an initial wave of pandemic-related waivers and flexibilities, adapting the process as necessary to the current pandemic emergency. However, we note that each future administration may adopt different distinct clearance processes and may require fewer, different, or additional approvals before issuance.

1. In advance of a pandemic, emergency response coordinators in each Center (for example, Provider Billing Group in CM – FFS) alert Center group directors to prepare their respective waivers.
    a. Blanket waivers for consideration in advance of the disaster may cover Medicare-FFS policies, appeals, provider enrollment, and conditions of participation. **NOTE:** CMCS may also consider implementing Medicaid blanket waivers for providers and beneficiaries.
    b. Each Center may follow established SOPs for collecting input from Center group directors.
    c. Upon review by CMS Centers, the "standard" set of disaster response waivers and flexibilities in each Center will be further refined from the existing set of natural disaster waivers and flexibilities and those additional waivers and flexibilities approved during the COVID-19 pandemic.
2. The applicable policy area in each Center drafts applicable waivers and sends the waivers to their respective emergency response coordinators.
3. Emergency response coordinators in each Center share the compiled list of blanket waivers with the Waiver Work Group for review and discussion. The Waiver Work Group may also discuss any potential program integrity concerns and may discuss how waiver proposals from one Center might relate to other programs (e.g., evaluate opportunities for consistent, enterprise-wide approach to policy changes for Medicare, Medicaid, CHIP, and the Health Insurance Marketplaces®[8]). The Waiver Work Group may also consider the impact of proposed waivers on vulnerable populations.

[8] Health Insurance Marketplace is a registered service mark of HHS.

4. As recommended by the Waiver Work Group, representatives from the Waiver Work Group or Centers present agreed-upon blanket waivers to the Office of the Administrator (OA) for approval.
5. After receiving approval, emergency response coordinators work with Center representatives to finalize and send waivers to Office of General Counsel (OGC) via email for clearance.
6. Once OGC cleared documents proceed through the CMS internal process to ensure Section 508 Compliance.
7. Approved waivers and flexibilities are posted to the CMS/Emergency Preparedness and Response Operations (EPRO) website (e.g., "Current Emergencies" page). Waivers and flexibilities will be communicated to CMS field staff working directly with providers to ensure timely and active receipt of policy changes at all CMS staff levels; in prior pandemic events, CMS field staff have been notified through emails associated with Office of Communications (OC) policy rollouts.
8. As needed, Center representatives will issue a Technical Direction Letter (TDL) advising the Medicare Administrative Contractors (MACs) of the declared PHE and providing direction on the implementation of waivers in the impacted areas.

Medicare Pandemic Blanket Waiver Inquiry Response Process

After issuing standard disaster response waivers according to the process detailed above and documented at Current emergencies, CMS anticipates receiving a large volume of additional blanket waiver requests as a result of the emergency. To respond, CMS may establish a dedicated 1135 Medicare waiver response team to triage and address incoming requests. During the COVID-19 pandemic, the dedicated team utilized the process outlined below to track and respond to waiver requests. As of November 2020, CMS was in the early stages of migrating to a web-based waiver inquiry submission form, and the process below will need to be adjusted to accommodate this change.

Examples from COVID-19 Response
The dedicated 1135 waiver response team established during the COVID-19 response followed the process below to respond to over 3,500 waiver requests: 1. Receive incoming waiver request from one of three primary sources: a. 1135 waiver mailbox (operated by CCSQ and OPOLE). b. Direct mail to CMS leadership, component-specific mailboxes, or HHS mailboxes (managed by OSORA). c. Internally-generated waivers or flexibilities (e.g., blanket waivers suggested by CMS SMEs or leadership but not included in the "standard set" of disaster response waivers). 2. Extract waiver request letters from incoming communications and catalogue request in central waiver request tracking document. Please see Annex C for example tracker provided by the COVID-19 1135 waiver response team. 3. Distribute synthesized details of request ("triage table") to programmatic senior advisors and select group of CMS SMEs for initial comment. Senior advisors and SMEs may be segmented into "pipelines" to address different waiver topics. a. SMEs and 1135 waiver response team may mutually agree on acceptable timeframes for revision before waiver request is discussed with Waiver Work Group.

Examples from COVID-19 Response
4. The Waiver Work Group meets daily to assess aggregated waiver and flexibility requests after review by CMS senior advisors and SMEs. See Section 7 (Direction, Command, and Control) for additional information on the composition and stand-up of the Waiver Work Group. 5. If approved by the Waiver Work Group, a representative from the responsible component (as determined by waiver topic) presents the recommended policy action(s) to the Administrator for expedited approval. 6. When approved by the Administrator, the responsible component finalizes waiver language. 7. The responsible component then engages in discussion with OGC as needed for final approval. OGC may recommend that other HHS components or OMB provide input on the approval, as needed. 8. If necessary, the responsible component may bring the waiver request back to the Waiver Work Group for additional comment during the approval and clearance process, if needed. 9. The responsible component (in collaboration with OC and the 1135 waiver response team) publishes the waiver on CMS/EPRO's website (e.g., "Current Emergencies" page) and issues a Technical Direction Letter (TDL) to advise MACs and provide direction on the implementation of the waivers.

Medicare Individual Waiver Inquiry Response Process

During a disaster, emergency, or pandemic event, CMS anticipates receiving individual waiver requests from providers around the country who experience unique challenges in providing continued access to care that are not addressed through blanket waivers issued by the Agency. In these circumstances, providers will submit most requests to CMS Locations or the CMS National 1135 Waiver mailbox at 1135Waiver@cms.hhs.gov for additional relief; requests for waivers under the physician self-referral law (Stark Law) are handled centrally by CM staff and should be submitted to 1877CallCenter@cms.hhs.gov. To address these requests, CMS may follow the process outlined below, adapted as needed to the current disaster, emergency, or pandemic:

1. Individual waiver request is received through direct mail to a CMS mailbox, CMS location, or the CMS National 1135 Waiver mailbox. Requests to operate under waiver authority should include a justification for the request and the expected duration of the modification requested.
2. A dedicated team in each CMS Location (in partnership with State Survey agencies, as needed) reviews the request.
    a. If a previously issued blanket or individual waiver applies to the request, the CMS Location may clarify the authority that already exists in the blanket waiver to respond to the request immediately.
    b. If previously issued blanket or individual waivers do not apply to the request, the CMS Location may approve or disapprove the request on a case-by-case basis where they have the authority to do so, considering the provider's justification and consulting with CMS SMEs in the CMS Location and in Baltimore as needed.
3. CMS Locations notify the requester of approval/disapproval. In cases of approval, providers are asked to maintain careful records of services provided to beneficiaries to ensure proper payment can be rendered. The CMS Locations (under the direction of CCSQ – Survey Operations Group) issues waiver letters to the provider(s) and sends copies to the appropriate Medicare Administrative Contractor (MAC).

Medicaid and CHIP Pandemic Waiver, Flexibility Request, and Adjudication Process

During a pandemic, CMCS will proactively reach out to state Medicaid and CHIP agencies to assess their needs and share information about available federal flexibilities and the process to request them. As part of initial communications with states, CMS will also distribute the Medicaid and CHIP Disaster Relief Toolkit that describes the range of waivers and flexibilities available to states. CMCS will also prepare to respond to incoming requests from states, the District of Columbia, and territories across the authorities (listed in Section 4.2.1 above) through which states and territories may request waivers and flexibilities. CMCS may leverage the following process, adapting as needed to the specific pandemic:

1. Stand up CMCS teams for each of the authorities, leveraging subject matter expertise within the Center and establishes a Triage Team to assess crosscutting submissions.
2. Evaluate whether templates/checklists leveraged in previous emergency response efforts are applicable; if so, distribute templates/checklists on Medicaid.gov and through applicable CMCS listservs.
3. If existing templates or checklists are not applicable, consider modification or development of additional templates.
4. Receive incoming state requests through established process (e.g., State Plan Amendments have a dedicated online submission process) or through direct email inquiries to CMCS or the broader Agency.
5. The Triage Team reviews submissions for flexibilities across multiple authorities while other teams review requests by individual authority.
6. Assigned team reviews request:
    a. If covered by template/checklist flexibility and existing policy, request may be approved through adjudication process for the authority.
    b. If policy requests or precedent are not covered, staff raises issue to CMCS leadership for final decision. CMCS leadership keeps the OA informed of state requests, actions, and policy decisions.
7. After review, assigned team communicates approval or disapproval of request to requesting state or territory. If disapproved, team provides suggestions of alternative available flexibilities.

During the COVID-19 response, CMCS staff developed templates/checklists for the authorities listed below for reference and use in future pandemic response. The full text of these templates can be found here: Coronavirus waivers & flexibilities.

Please see Annex K for CMCS Strategic Planning Framework for use in responding to a public health emergency.

4.3 Other Areas of Policy Action

4.3.1 Clinical Standards and Quality Initiatives

The Center for Clinical Standards and Quality (CCSQ) will lead the Agency's response to ensure appropriate health and safety standards are maintained by Medicare, Medicaid, and CHIP

providers during a pandemic and are augmented as necessary in order to address new challenges in meeting these standards during a pandemic event. In addition to supporting the development and issuance of waivers and flexibilities (documented in preceding sections), CCSQ may coordinate additional Agency activities across several dimensions related to clinical standards and quality initiatives, including:

- Survey prioritization and infection control.
- Coordination of testing efforts and infection control guidance with the CDC and other federal Agencies.
- Reinforcing additional flexibilities via administrative memo.

Survey Prioritization & Infection Control

CMS may issue waivers, revise its rules, or release additional, specific updated guidance (as applicable) on infection control in targeted settings and for state and federal surveyors to prioritize complaints and other survey activities concerning the current pandemic. For example, CMS may:

- Prioritize federal surveys to focus on infection control and complaint investigations at the Immediate Jeopardy level.
- Modify or suspend enforcement cycles based on survey prioritization activities.
- Develop focused inspection tools for a variety of healthcare settings to operationalize latest guidance from CMS and CDC.
- Issue guidance to providers in a variety of healthcare settings to address frequently asked questions and provide additional recommendations on infection control best practices.
- Increase penalties for non-compliance with infection control requirements.
- Modify visitation requirements or guidelines in targeted settings.
- Conduct additional off-site surveys of providers caring for vulnerable populations to assist in self-assessing infection control protocols.

CCSQ may partner with other CMS Centers and Offices (e.g., with the Office of Security, Facilities, and Logistics Operations (OSFLO) to procure PPE for federal surveyors) and as appropriate with State survey agencies to execute the actions above. CMS has in place a general process that includes an ad hoc agency-wide call for financial resources necessary to support a pandemic. This process includes requests for supplemental resources for any unmet needs within and beyond the agency's available appropriation. In addition, CCSQ may work with the Office of Financial Management (OFM) to develop supplemental budget requests or reallocation of existing funds, as needed, to address challenges during a pandemic.

Coordination of Infection Control Guidance and Testing Efforts With The CDC

CMS may also coordinate closely with the CDC and other federal agencies to monitor screening and/or diagnostic testing efforts across the nation and to ensure consistent guidelines on addressing the pandemic are published and operationalized. CMS plays a critical role in amplifying and distributing CDC guidance on infection control and other pandemic-specific

health protocols to its broad network of providers and beneficiaries. Coordination efforts will build on existing relationships between CCSQ and CDC staff, and CCSQ may consider increasing the frequency of regular cross-agency touchpoints, further partnering with the CDC's federal disease surveillance system, or deploying an infection prevention specialist to CDC's Atlanta headquarters to assist with real-time development of guidance. Additional efforts may include coordination with the CDC to monitor, guide, and support state, local, and facility level infection prevention and control preparedness and response capacity.

NOTE: CMS expects to also coordinate with the CDC and other federal agencies on the Agency's internal, operational response to the pandemic (e.g., workforce guidance and norms). Please see Section 7: Direction, Control, and Coordination for additional details on this aspect of the response.

Examples from COVID-19 Response

CCSQ conducted critical activities to ensure the health and safety of vulnerable populations in CMS' 15,400 Medicare and Medicaid nursing homes during the COVID-19 pandemic, including:
• Hosting weekly stakeholder engagement calls with nursing home providers across the country. (See Section 5 below for additional details).
• Partnering with States to conduct Focused Infection Control surveys, ultimately implementing performance-based funding requirements associated with the completion of these surveys to inform allocation of CARES Act funding.
• Requiring nursing homes to report positive cases of pandemic infection to both state and local health officials and to the CDC.
• Posting on CMS' website COVID-19 data submitted by facilities via the CDC's National Healthcare Safety Networks (NHSN).
• Developing toolkits and issuing guidance to nursing homes, including best practices on infection control, workforce and staffing and frequently asked questions for long-term care facilities. CMS issued over 70 guidance documents and fact sheets related to infection control between February 2020 and December 2020.
• Conducting phone surveys of nursing homes to assist in self-assessing infection control protocols in partnership with OPOLE clinicians.
• Enhancing enforcement remedies for non-compliance with infection control protocols, including civil money penalties (CMPs).
• Reimagining the role of Quality Improvement Organizations (QIOs) in providing technical support to nursing homes and others to address needs identified during the pandemic:
  o Refocusing QIO on providing education and training and assisting in creating infection control action plans, including weekly National Infection Control Training.
  o Enabling QIOs to provide direct assistance to small and rural nursing homes and those serving vulnerable populations to comply with CDC and CMS reporting requirements and, in some cases, to provide on-site support to those with the greatest needs in infection control (e.g., those with significant needs or previous outbreaks).
• Holding nursing home five-star quality ratings constant during the suspension of typical survey activities.
• Publishing a list of the number of nursing and total staff that work in each nursing home each day to assist in the allocation of PPE.
• Posting the results of surveys conducted in nursing homes during the PHE on CMS' Nursing Homes Compare website.

4.3.2 Caring For Vulnerable Populations

As the leading healthcare and oversight provider for many of the nation's most vulnerable, CMS is responsible for ensuring the health and safety of these populations during a pandemic. The particular population most affected might vary in a given pandemic; vulnerable populations under consideration may include: racial and ethnic minority populations; long-term care facility residents (including nursing home residents), those with underlying chronic conditions (e.g., individuals on dialysis); individuals with intellectual, physical, or developmental disabilities; and dually enrolled Medicare and Medicaid beneficiaries, among others.

CCSQ, the Federal Coordinated Health Care Office (FCHCO), and the CMS Office of Minority Health (OMH) will lead CMS' efforts to engage with and assist vulnerable populations. CMS may engage in activities in two primary areas to accomplish this goal:

1. Engaging in emergency policy development and implementation.
2. Issuing additional guidance and conducting additional outreach and education.

Early in the response effort, CMS should assess the need for developing a comprehensive plan for addressing health disparities during the pandemic. The plan may include actions across both areas identified above.

Engaging In Emergency Policy Development and Implementation

CCSQ, FCHCO, and OMH will participate in the Waiver Work Group and equivalent structures (e.g., Emergency Management group, Policy Response groups, Communications, Outreach, & Legislation groups) to ensure emergency policy development and implementation activities consider and protect vulnerable populations. In doing so, these Centers and Offices may:

- Identify populations that are vulnerable to health disparities during a pandemic and any potential barriers that are actionable by CMS, and develop policies and resources that are responsive to addressing these barriers.
- Assess the impact of proposed waivers and flexibilities (e.g., telehealth) on ensuring continued access to care for vulnerable populations and to identify any barriers these flexibilities might create.
- Provide feedback to the Waiver Work Group during the discussion, review, and clearance processes to mitigate barriers as needed.
- Collaborate with other Centers to develop additional waivers, flexibilities, or program changes to address barriers identified above, or to address program changes unique to vulnerable populations.
- Assist in coordinating waivers and flexibilities issued by different program areas (e.g., Medicare and Medicaid) that may create program misalignments or complexities in serving vulnerable populations.

Issuing Additional Guidance and Conducting Additional Outreach and Education

In addition to engaging in policy development and implementation activities, these Centers and Offices will ensure that program and policy changes are effectively communicated to and

shaped by vulnerable populations. In addition, CMS will remind covered entities of their continued obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, and sex in HHS-funded programs. These Centers and Offices may:

- Take reasonable steps to provide meaningful access to individuals with limited English proficiency (LEP) in their area. Reasonable steps may include written translations of documents, or oral language assistance from a qualified interpreter, either in-person or using remote communication technology.
- Amplify CDC communications to beneficiaries, ensuring that published materials are culturally and linguistically appropriate and accessible for CMS beneficiaries (e.g., appropriate reading level, graphics including minority and vulnerable populations, information provided in plain languages and in the non-English languages prevalent in the affected areas in various media forms).
- Evaluate opportunities to expand stakeholder engagement outreach efforts (see Section 5 below) to include beneficiary advocacy groups and other stakeholders particularly servicing vulnerable populations and/or the providers who care for them.
- Hold targeted listening sessions with providers representing vulnerable populations to understand their unique challenges and concerns, potentially in coordination with CDC, Health Resources and Services Administration (HRSA), or other federal agencies serving similar populations. CMS may also hold targeted listening session focused on priority populations, sexual and gender minorities, individuals with limited English proficiency, and others whose experiences or social determinants may present unique challenges.
- 800-Medicare would remain fully available to Medicare beneficiaries during a pandemic response. The call center would provide information to callers on a range of topics including Medicare specific information and amplifying CDC messaging on how to stay safe. Top call topics would include questions about telehealth, Medicare coverage of additional testing types, and information on deferring paying premiums for those out of work.
- Healthcare.gov and the Marketplace call centers would also remain fully available during and pandemic and language on the website and scripts would be updated on a range of topics including Marketplace specific information amplifying CDC messaging and changes to eligibility on enrollment in the pandemic. Top topics include telehealth, coverage for testing, special enrollment periods and how unemployment income would be incorporated into eligibility determinations.

During the COVID-19 pandemic, CMS acted to care for particularly vulnerable populations in nursing homes. Examples of the actions taken to assist this population are documented below and may be applicable to vulnerable populations in future pandemics.

4.3.3 Provider, Program Integrity, Supplier, and Beneficiary Enrollment and Eligibility Policy

In modifying provider and beneficiary enrollment processes to respond to the pandemic, CMS hopes to find a balance between relaxing certain requirements to enable more healthcare providers and beneficiaries to supply and access care and maintaining enrollment requirements in order to prevent fraud, waste, and abuse in the Medicare and Medicaid programs. Furthermore, as waivers and flexibilities are provided, CMS will review and evaluate each of them for potential vulnerabilities and determine strategies to mitigate those vulnerabilities.

The Center for Program Integrity (CPI) will evaluate numerous mechanisms for reducing provider burden and enhancing beneficiary access-to-care through provider enrollment during the pandemic. For instance, CPI may consider the following activities in response to the pandemic (the below bullets pertain to Medicare enrollment unless otherwise stated):

- Expediting new and pending enrollment applications.
- Determining if any data verifications should not be performed to reduce provider burden to expedite the enrollment process. Examples include verifications of phone numbers, incorporation dates, business licenses, and changes of address.
- Waiving certain regulatory enrollment requirements for all providers and suppliers such as physical practice location site visits for newly enrolling moderate and high-risk providers/suppliers and postponing revalidation activities (a periodic recertification of the accuracy of the enrollment record, which may include a site visit).
- Waiving certain regulatory requirements for specific providers and suppliers such as the Durable Medical Equipment Prosthetics, Orthotics, andSupplies (DMEPOS) accreditation requirement for newly enrolling DMEPOS suppliers and the fingerprint requirement for 5% or greater owners of newly enrolling home health agencies, DMEPOS suppliers, Medicare Diabetes Prevention Program suppliers, and Opioid Treatment Program providers.
- Waiving certain regulatory requirements pertaining to Medicaid enrollment such as site visits and revalidation (similar to Medicare).
- Considering whether immediate provider enrollment regulatory changes via an interim final rule would be appropriate.
- Establishing a hotline enrollment process where practitioners and certain types of providers and suppliers can enroll over the phone and immediately receive temporary billing privileges.
  - **NOTE:** CM – FFS: Provider Communications Group has previously established emergency toll-free phone line instructions to allow hotlines to be activated within 48 hours of a disaster or national emergency. The hotlines are administered by the MACs and can support recording audio and video.
- Reviewing all current regulatory authorities to determine which provisions are triggered by the pandemic. For instance, Special Purpose Renal Dialysis Facilities (SPRDFs) are permitted to enroll under emergency circumstances to serve End-

Stage Renal Disease (ESRD) beneficiaries. See 42 C.F.R. § 494.120 for additional information.

As CPI evaluates the activities above to expand provider enrollment, CM, CMCS, and CCIIO may consider similar activities to enable more beneficiaries to enroll in CMS programs and access care, including adjusted enrollment windows, additional enrollment assistance (e.g., through hotlines), and modified or waived disenrollment policies.

4.3.4 Program Integrity and Evaluation

In issuing policy changes to respond to the pandemic, CMS will also act to protect its programs and beneficiaries from fraud, waste, and abuse, as well as to prepare for audits and oversight activities that may follow an emergency response.

The Center for Program Integrity (CPI) has developed a robust program integrity evaluation process, utilizing the Government Accountability Office Fraud Risk Framework, for waivers and flexibilities that may be adapted for future pandemic events. As part of this process, CPI may use a comprehensive analysis that documents each approved waiver and flexibility that the Center determines to have program integrity implications due to the potential for waste, fraud, and abuse. The comprehensive analysis may include the following information:

- A description of the waiver or flexibility service category (e.g., telehealth, home health, durable medical equipment, etc.) that is being evaluated.
- Specific waivers or flexibilities granted by CMS.
- Impacted provider group(s).
- Authority under which waivers or flexibilities were issued, including link to source document.
- Impact of the waivers and flexibilities, including financial and/or patient harm.
- Potential vulnerabilities identified by CPI.
- Vulnerability risk level for specified elements, incl. financial, likelihood, patient harm, overall.
- Mitigation strategies, including timeframe, milestones, and status of strategies.
- Waivers and flexibilities permanency recommendations.

In addition to carefully documenting risks and mitigation strategies in CPI, CMS Centers and Offices will take additional proactive steps to mitigate risk and anticipate audit and other oversight activities, including but not limited to:

- Encouraging open and ongoing discussion in response governance bodies (e.g., Waiver Work Group) on program integrity risks.
- Ensuring CPI provides early input on Interim Final Rules and other policy documents during the clearance process.
- Making necessary systems changes to “tag” or categorize transactions and activities related to the pandemic response so that future program integrity oversight efforts can be appropriately tailored.

- Proactively commissioning internal audits of financial support programs like Accelerated and Advance Payments before the regular review cycle.
- Conducting fraud, waste and abuse investigations and implementing appropriate administrative actions.
- Collaborating with the Office of the Inspector General and other law enforcement agencies on investigations/potential fraud schemes.

4.3.5 Value-Based Payment Policies (Including Quality and Financial Measurement and Performance)

In response to a pandemic event, CMS may make adjustments to the Agency's value-based payment initiatives, including the Medicare Shared Savings Program, and quality rating systems to allow healthcare providers, healthcare facilities, Medicare Advantage and Part D plans, and States to focus on providing needed care to beneficiaries. Some of these changes may be included in Extreme and Uncontrollable Circumstances policies for the payment initiative or quality rating system; examples of potential changes to value-based payment policies include but are not limited to:

- Mitigating shared losses for Accountable Care Organizations (ACOs) participating in a performance-based risk track based on the length of the Public Health Emergency.
- Extending quality reporting period deadlines and adjusting quality scores or rating methodologies.
- Adjusting, forgoing, or delaying application cycles.
- Implementing agreement extensions for current participants.
- Delaying automatic advancement to increased performance risk where applicable.
- Adding billing codes specific to pandemic-related waivers and flexibilities to maintain patient alignment.

CMS may implement similar changes not already reflected in the existing Extreme and Uncontrollable Circumstances policies through the issuance of IFCs or amendments to participation agreements during the pandemic. CMS would communicate any relevant changes that have been adopted either unilaterally or by mutual consent through a participation agreement or through an IFC, through existing model communication channels, including emailing participants, as well as other guidance, and stakeholder engagement forums.

4.3.6 Accelerated and Advance Payment Programs

When addressing a PHE, such as a pandemic, CMS may prepare to increase cash flow to the provider and supplier communities by exercising authority to expand the existing Accelerated and Advance Payment programs to Medicare Part A providers and Part B suppliers nationwide, under §1815(f) of the Social Security Act and 42 CFR §421.214(j). Accelerated and Advance Payments have previously been funded from the Hospital Insurance (Part A) and Supplementary Medical Insurance (Part B) Trust Funds, the same funds used to pay out day-to-day Medicare claims. Given that these payments will affect the solvency of the HI trust fund

and the premium and other financing for Part B, the Office of the Actuary should be engaged during the policy development.

Provider Approval and Disbursement Process

To rapidly disburse payments to providers and suppliers in response to a pandemic event, eligibility criteria for the Accelerated and Advance Payment programs apply. The following process was utilized during the COVID-19 pandemic consistent with applicable authorities and may be adapted to future emergency situations as needed.

Examples from COVID-19 Response
1. Providers and suppliers submitted a Request for Accelerated/Advance Payment to their regional Medicare Administrative Contractor (MAC) by fax, email, or mail. a. In order to be eligible for the program, providers/suppliers needed to meet certain criteria determined by CMS. For example, providers/suppliers must have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/supplier's request form. OFM also relied on preexisting Center for Program Integrity (CPI) review procedures to determine if providers/suppliers were eligible to receive accelerated or advance payments and worked with CM-MCMG to issue a TDL to the MACs directing how to execute against those criteria. Subsequently, OFM collaborated with CPI after AAP payments were issued to review MAC and UPIC determinations as a continued oversight function. b. The request was signed by the provider's/supplier's authorized official that is legally able to make financial commitments and assume financial obligations on behalf of the provider/supplier. Providers /suppliers that are part of a group practice were able to attach a list of Provider Transaction Access Number (PTANs)/National Provider Identifier (NPIs) to the form. The authorized representative required authority to sign on behalf of all parties included in the list. 2. Providers were asked to request a specific amount of payment. Most providers and suppliers were able to request up to 100% of the Medicare payment amount for a three-month period. Inpatient acute care hospitals, children's hospitals, and certain cancer hospitals were able to request up to 100% of the Medicare payment amount for a six-month period. Critical access hospitals (CAH) were able to request up to 125% of their payment amount for a six-month period. 3. Each MAC generally reviewed and issued payments within 10 days of receiving the request. MACs were responsible for determining provider eligibility in accordance with guidance issued by CMS.

Contractors may track the processing of accelerated and advance payment requests related to the pandemic and may submit daily and weekly status reports to the relevant CMS staff. During the PHE, providers/suppliers do not have administrative appeal rights related to whether or not CMS made these payments.

4.4 Supporting Policy Activities

4.4.1 (Section Intentionally Removed)

4.4.2 (Section Intentionally Removed)

4.5 Reconstitution Activities To Assess Approved Waivers and Flexibilities

NOTE: Unwinding activities, including permanency recommendations and roll back plans for approved COVID-19 waivers and flexibilities, are still in progress. When these efforts are complete, this section of the pandemic plan will be updated to include documentation and templates critical to these processes.

5 Engagement of External Stakeholders

To achieve CMS' dual goals of ensuring continuous access to care for beneficiaries and providing providers with timely payment of claims, CMS may launch a thorough effort to engage and inform industry stakeholders in the beginning stages of a pandemic and when any policy actions are anticipated.

CMS policy personnel expect to engage industry stakeholders to keep them apprised of policy changes, issuance of waivers and flexibilities, and other critical policy information released by CMS; stakeholder engagement efforts will also help to keep CMS apprised of the needs of beneficiaries, providers, and payers. The section below details the support approach, process, and forums for engaging external stakeholders based on effective procedures established in the COVID-19 response. Stakeholder engagement may be run out of the OA and should operate in close coordination with the Centers, Offices, and the Pandemic Working Group referenced in Section 8 of the pandemic plan.

5.1 Scope of Stakeholder Engagement

Engagement may target the full scope of critical industry stakeholders including: Physician providers, non-physician providers (including nurses, therapists, physician assistants, pharmacists, clinical laboratory scientists, and lab technicians), hospitals, ambulatory care facilities, nursing homes & facilities, home health & hospice agencies, specialty facilities (SNFs, dialysis & kidney centers, and rehab facilities), medical equipment manufacturers, Insurers and other financial institutions and medical and professional associations. Under the authority of CMCS, the Agency may also engage state Medicaid and CHIP directors and representatives. CMS may also collaborate with beneficiary advocacy groups and other representatives of vulnerable populations, including medical societies representing minority populations, rural healthcare providers, and others. Led by the Office of Program Operations and Local Engagement (OPOLE), CMS may also communicate with local stakeholders including provider organizations, beneficiary organizations, and local Congressional offices to keep communication lines open. Additionally, CMS may coordinate with federal agency partners to synchronize efforts, and ensure aligned messages and complementary outreach.

Timely communication of policy actions regarding waivers and flexibilities may be contemporaneously provided and updated to keep industry stakeholders abreast of changes in policy and to provide clarity on newly issued flexibilities and waivers.

5.2 Forums for Stakeholder Engagement

Stakeholder engagement efforts may establish forums to inform industry of CMS policy changes, address questions on flexibilities and waivers, and disseminate best practices during the pandemic response. The stakeholder engagement lead may work with CMS leadership to determine the appropriate frequency and types of forums to engage with stakeholders, which can flexibly evolve as the pandemic response adapts over time. Once determined, the invites and links for these forums may be circulated broadly using CMS websites as well as notifications

to stakeholders subscribed to CMS' open forums e-mail list or other relevant listservs (including Medicaid listservs).

A flexible approach will be used to leverage CMS' network of connections to the broad set of stakeholders, and this approach may be determined by the nature of the pandemic. Examples for the COVID-19 response are detailed below.

Examples from COVID-19 Response
For the COVID-19 response, given that virtually all aspects of healthcare delivery were directly impacted by COVID-19, a broad set of forums were initially established to enable any and all stakeholders to engage with CMS. Example forums are provided below based on effective communication channels used during the COVID Pandemic: • **Office Hours –** Open forum for providers and stakeholders to participate in technical Q&A with CMS subject matter experts (SMEs), and to enable CMS SMEs to provide updates on recent issuances of policy or guidance and direct stakeholders to critical documentation. • **Provider calls** – Calls to allow providers to share best practices from their sites in navigating the pandemic and to enable peers to ask questions of speakers, driving peer-to-peer learning. • **Front Lines** – Forum for CMS and other agencies to share pandemic updates and for industry stakeholders to share learnings from the front lines of the pandemic, including Q&A sections designed to drive peer-to-peer learning. • **Open forums with state Medicaid and CHIP directors –** Calls to address inquiries, distribute disaster-related resources, and share best practices among state Medicaid and CHIP staff. • **Targeted calls with states and territories –** Calls with individual state Medicaid and CHIP directors and their staffs in all 56 states and territories to understand unique concerns and to connect states and territories with CMCS SMEs as needed. Other calls with state officials may also focus on individual state small group and individual market concerns or the state department of insurance to understand unique concerns relating to these markets with CCIIO SMEs as needed. • **Targeted calls with insurers –** Calls with individual insurers participating in the Marketplace to understand unique challenges and concerns with CCIIO SMEs. These calls may also be conducted with associations representing insurers. • • **Ad-hoc discussions -** Small, targeted discussions and listening sessions with various associations and stakeholders on CMS' pandemic response, designed to facilitate understanding of how CMS could better support each specific stakeholder group. • **Local engagement efforts-** Continuation of informal local engagement efforts targeting regional provider, beneficiary, and government groups.

As the pandemic progresses and the situation stabilizes, the frequency of several large-scale calls may decrease. Stakeholder engagement efforts may then shift towards one-on-one, small group discussions with targeted stakeholder groups (e.g., American Medical Association, American College of Surgeons, etc.). These discussions may be scheduled on an as-needed basis to enable stakeholders to share the context and detail around their unique concerns and allowed CMS and stakeholders to align on a path forward to continue discussing evolving policies during the pandemic.

The exact cadence and frequency for holding forums may be determined and adjusted based on the intensity of stakeholder feedback. A minimum of two CMS personnel are expected to attend each forum in order to capture notes on best practices shared and stakeholder questions. After each call, the CMS group may produce a deliverable that synthesizes best

practices and key issues raised by stakeholders (see Table 1). Issues may be consolidated into a Weekly Stakeholder Engagement Report that is shared with CMS pandemic response leadership. Stakeholder engagement may also share call transcripts with industry and the public at large.

To ensure efficient resolution of outstanding issues arising from stakeholder forums, CMS personnel may document and track "Open issues" to be addressed by CMS SMEs. When possible, Open Issues can be addressed in follow-up calls through either 1) verbal description of new policies or updates that pertain to the initial issue raised, or 2) directing stakeholders to latest issuances on CMS or other agency webpages.

Table: Examples from COVID-19 Response: Stakeholder Calls and Deliverables

Call	Deliverable	Description	Report Sections
Office Hours	**Summary, takeaways, & Q&A report**	Captures all Q&A to CMS SMEs during Office Hours and synthesizes key takeaways to provide a high-level view of stakeholder priorities, and propose next steps to address issues when possible.	• Topics – brief list of top 4-5 topics raised. • Key takeaways – Synthesized view of questions and issues raised. • Potential next steps – Actions to address open issues. • Summary of entire Q&A session.
Provider Calls	**Summary & best practices report**	Summarizes best practices shared by providers on each call. Calls generally focus on providers practicing at specific healthcare sites (e.g., hospice agencies) or those working in specific specialties (e.g., dialysis and kidney).	• Best practices, organized by guest speaker. • Summary of Q&A from callers to speaker. • Summary of Q&A from callers to CMS.

Call	Deliverable	Description	Report Sections
Front Lines	**Summary, takeaways, & best practices shared report**	Summarizes updates from other federal agencies (FDA, HHS, etc.), synthesizes best practices shared by providers from the field, and captures issues and questions raised by stakeholders attending the call.	• Updates from federal agencies. • Best practices from providers, organized by key topics (e.g., further promote telehealth, etc.), including: o CMS "Office Hours" on COVID-19 – regular calls with hospitals, health systems, and providers to ask questions of agency officials regarding CMS's regulatory relief in response to COVID-19. o Open Door Forums (ODF) Telehealth, Waivers and State flexibilities. o Weekly COVID-19 stakeholder call with Nursing Homes. o Weekly COVID-19 stakeholder call with Dialysis/Kidney Organizations. • Summary of Q&A from stakeholders.
All calls	**Weekly summary report**	Summarizes best practices shared and key issues raised during all external stakeholder calls held during the preceding week in a format designed to make takeaways clear to senior leaders.	• Summary of Best Practices. • Key takeaways from Office Hours. • Key issues raised by stakeholders during provider calls. • Summary of stakeholder reactions to CMS' recent activity.

5.3 Rapid Response Correspondence Process

In a pandemic or other public health emergency, CMS may consider implementing a rapid response correspondence team to address Congressional letters, letters from medical associations and provider groups, and other written stakeholder inquiries. CMS expects the volume of these correspondence documents to dramatically increase at the onset of the emergency and as emergency waivers, flexibilities, and guidance are issued. In previous emergency responses, including Hurricane Katrina and the COVID-19 pandemic, Office of Strategic Operations and Regulatory Affairs (OSORA) has coordinated a rapid response team to

respond to these written inquiries. OSORA may leverage the following rapid response correspondence process, adapted as needed to the current pandemic:

1. Non-Medicaid and non-quality beneficiary/provider casework is assigned to regional offices, CCSQ, or CMCS consistent with normal procedures.
2. All incoming correspondence related to the pandemic is labelled as such in the subject line for easy identification for regional and component rapid response triage teams, identified individually by regions or components.
3. OSORA triages and adjusts time frames for responses to incoming correspondence according to the following:
    a. If the incoming correspondence is a Congressional letter that requires a CMS response, OSORA assigns the action to OL to author a draft response that will be cleared through normal channels before submitting to OA for approval. If a Report of Contact (ROC) is received from OL, OSORA closes the record. OL may request assistance from or reassignment to other component SMEs as needed.
    b. (This section intentionally removed).
    c. If the incoming correspondence is a non-Congressional letter (e.g., from other policy officials or stakeholder organizations), OSORA assigns the letter to the lead policy component or regional rapid response team to draft a response.
4. OSORA clearly communicates escalation process to central and regional offices if receiving correspondence addressed to senior officials, including what documents should be escalated (e.g., letters) and which should not (e.g., 1135 waiver requests).
5. OSORA works with OA, OL, and HHS/OS leadership to prioritize which PHE letters/topics are sensitive and/or require rapid, coordinated, or delayed responses, or in some instances, no response at all.
6. OSORA works with OA, OL, OGC, OC and HHS/OS on developing and clearing standard language that components and/or regions can use to rapidly respond to letters on recurring topics.
7. OSORA provides weekly reports on incoming Congressional and other stakeholder correspondence to OA and the pandemic/PHE coordinator.

5.4 Inquiry Response and Help Desk

To prepare to respond to incoming inquiries from external stakeholders on the pandemic and CMS’ policy response, the Agency may consider establishing a centralized pandemic intake point with supporting inquiry response team. The location of this centralized pandemic resource (e.g., location of a web form on CMS’ emergency response website) should be shared with external stakeholders in calls with CMS and in published guidance materials.

In the most recent pandemic event, OPOLE effectively staffed an inquiry response team, a Customer Relations Management tool was developed to effectively intake, triage, and track incoming inquiries. . The inquiry response, or “helpdesk” team, may leverage the following process during future pandemics to respond to helpdesk inquiries, modified to fit the current pandemic as needed:

1. Receive inquiry from one of the following sources:
    a. Secure web form on CMS' emergency declaration webpage.
    b. Direct mail to a single, centralized pandemic mailbox.
    c. Direct mail to a CMS senior official.
    d. Mail to another CMS mailbox (e.g., press mailbox, component-specific mailbox) and forwarded to a centralized pandemic mailbox.
2. ServiceNow module intakes inquiry, opens ticket, and triages the inquiry to the appropriate OPOLE team.
    a. OPOLE may establish 6-8 teams aligned to CMS Centers.
3. Appropriate OPOLE team receives inquiry and drafts response.
    a. Where possible, OPOLE team drafts response using published or cleared guidance.
    b. If guidance does not yet exist, OPOLE works with SMEs in relevant component to respond to inquiry.
4. Ticket is closed in ServiceNow system.

The OPOLE helpdesk team may coordinate with other ongoing stakeholder engagement efforts (e.g., office hours calls) to raise recurring inquiries and address pressing incoming questions in stakeholder outreach. The team may also collaborate closely with OA and with the Centers to share stakeholder feedback on issued guidance and to recommend additional guidance, as informed by incoming inquiries.

Examples from COVID-19 Response
During the COVID pandemic, stakeholder engagement outreach efforts effectively established feedback loops with the OPOLE-managed helpdesk and with OA by adhering to the process below in the handling of 5,206 inquiries from April – December 2020: • OPOLE fielded questions from a variety of stakeholders (e.g., physicians, medical equipment suppliers, Congressional offices, hospitals, medical associations, etc.) sent to the COVID-19 mailbox. • OPOLE provided questions to OA that were asked frequently and required responses that were not yet readily available. OPOLE and/or OA worked with CMS components/SMEs to track down responses to the questions. • Questions/responses were addressed at the beginning of stakeholder engagement outreach calls (e.g., Office Hours) during the week or were left open if additional research was needed. • OPOLE leveraged these verbal responses in developing their email replies to stakeholders in partnership with CMS SMEs. • Items addressed at the top of the call were closed out in the Policy Tool. • Routine analyses of COVID-19 inquiries were shared with OA to provide additional situational awareness from CMS' stakeholders and across its programs.

5.5 Internal Tracking of Stakeholder Concerns

Given the rapid pace of policy change in a pandemic, Stakeholder engagement outreach efforts may need to develop an effective system for tracking questions and answers arising from calls with industry stakeholders. This tool may take a variety of forms depending on the nature of the pandemic; one example of an Excel tool used during COVID-19 is detailed below.

Examples from COVID-19 Response
During the COVID pandemic, Stakeholder engagement utilized the Policy Issues Tool for this purpose. The Policy Issues Tool was an Excel document for maintaining an inventory of all questions and concerns arising from external stakeholders. Example outputs and links to the Policy Issues Tool are available in Annex D. The critical functions of a Policy Issues Tool include the following: 1. **Synthesis of individual questions into key topic categories** – Provides visibility into major priority areas for stakeholders and facilitates CMS' ability to quickly scan the inventory for questions that may fall under a similar theme. 2. **Tracking of issues by date and week** - Enables understanding of how policy issuances and publication of guidance from CMS either resolves and/or raises topics or requests from stakeholders – for example, during the COVID PHE, requests for telehealth flexibilities decreased after the issuance of the second Interim Final Rule, while questions about specific coding guidance for those services were steady in light of new flexibilities. 3. **Tracking of issue "status"** – Provides real-time view of which issues have been resolved during an engagement forum, or if further follow-up by CMS is needed. This enables CMS to address issues and develop new policies or guidance that address stakeholders' most pressing needs.

5.6 External Scan of Stakeholder Reactions

To obtain external perspectives on the effectiveness and impact of CMS policy actions, CMS may develop a system for capturing stakeholders' reactions online and in other forums to inform further policy-making decisions during the pandemic. The environmental scan may be conducted as an ongoing, ad-hoc process to assess external stakeholders' perspectives on topics of high priority for CMS. Scan results may be aggregated into weekly reports and synthesized into core themes. Example templates for the environmental scan leveraged in COVID-19 are included in Appendix D.

Examples from COVID-19 Response
The environmental scan process used in the COVID pandemic serves as an example. The scan consisted of a four-step process to capture and synthesize industry reactions to CMS policy changes: 1) **Align on topics** –Solicit input from the Policy working group to determine topic areas and/or specific flexibilities and waivers to prioritize in the scan. 2) **Capture statements** – Collect and collate industry press releases, blog posts, news articles and other relevant public statements to assess industry sentiment on the prioritized topics. 3) **Synthesize findings** – Document author type, medium (e.g., press release, news article), sentiment and key takeaways for each captured statement. 4) **Deliver final report** – Synthesize materials into the environmental scan template, including summaries of key takeaways by topic area and stakeholder type, and present report to the Policy Response team.

6 Operational Response

This section provides an overview of CMS' internal operational response to the pandemic. The Operational Response will focus on: 1) Enabling organizational alignment to execute the pandemic response and 2) Promoting the safety of CMS employees and the resilience of CMS systems.

6.1 Areas of Operational Response

CMS' internal operations will have to contend with multiple challenges arising from the pandemic. Risk of infection may make onsite work and collaboration prohibitive, necessitating several changes in operations. Additionally, any need to sustain the response effort for several months will require additional considerations and enablers.

The following categories account for the major dimensions of the operational response:

- Launch internal pandemic response.
    - **Stand-up of response governance structure** – Constitute response team structure (see Section 7: Direction, Control and Coordination).
    - **Prioritization of critical work** – Identify CMS' functions critical to the pandemic response and provide direct support to high priority initiatives, including re-evaluation and prioritization of existing contracts.
    - **Facilities & infection control** - Implement protection measures for onsite staff to ensure safe facilities and mitigate infectious risk.
- Activate enablers of the operational response.
    - **Workforce management** - Adjust workforce policies and flexibilities to enable alternative work arrangements and shift workforce capacity as needed.
    - **Internal communication** - Enhance existing internal communication channels and establish new lines of communication between employees and leadership.
    - **Contracting** - Enact procurement and contracting flexibilities to meet CMS' evolving staffing and supply needs (see also "Prioritization of critical work" for assessment of existing contracts).
    - **IT and systems** - Support and secure IT systems and solutions to enhance connectivity and protect CMS' IT infrastructure.

<u>**Launch Internal Pandemic Response**</u>

Standup of Response Governance Structure

To swiftly coordinate and act in response to the pandemic, CMS will need to establish a response structure that brings together policy and operational components to facilitate rapid decision-making and execution of the agency's pandemic response. In particular, the Administrator will need to assign representatives from relevant policy and operational components to key roles leading the pandemic response. See Section 7: Direction, Control, and Coordination for detailed information covering the governance structure.

The optimal configuration of the response structure may vary in future pandemics based on the intensity of the threat, the policy priorities of future administrations, or the length of the pandemic. The structure should be designed to identify and clarify roles and responsibilities and enact enablers to optimize efficient decision-making and rapid execution on priority initiatives.

Prioritization of Critical Work

Given the systemic workload pressures that arise during a pandemic, CMS may be required to prioritize work that is critical to maintain essential support activities.

To prioritize among work streams, CMS may engage in three assessments:

- **Critical Business Functions Assessment -** the Office of the Chief Operating Officer (COO) may instruct CMS' operational and programmatic components to review their inventory of critical business functions contained within the SOPs. Following the assessment, resources can be allocated to support activities that are essential to the continuity of the prioritized critical business functions.
- **Audit Assessment –** The Office of the COO can review planned and ongoing audits at CMS to identify audits to pause or modify.
- **Contracting/Procurement Assessment –** OAGM may initiate a review of existing contracts and procurements to identify contracts supporting ESAs to continue and halt or modify non-essential contracts to release funds that may be prioritized for pandemic-related work.

Facilities and Infection Control

Multiple infection control procedures may be needed to ensure the health and safety of personnel at CMS facilities. Several community mitigation techniques are available to accomplish this goal:

- Initiate strategies to minimize chances of workplace exposure (e.g., physical and social distancing, hand sanitizer stations, mask requirements, etc.) and follow infection control protocols strictly at all facilities based on guidance from public health officials.
- Restrict access to or temporarily close CMS facilities and maximize transition to alternate workplace locations and telework throughout the pandemic. Operational leadership should prepare and support all personnel in transitioning to alternate work arrangements (e.g., telework), where this occurs.
- Bolster PPE stock for CMS employees working in the field and collaborate with federal efforts to source additional PPE to maintain adequate minimum stockpiles of PPE.
- As needed, evaluate opportunities to make testing and vaccinations available to all employees.
- As needed, stand up Contact Tracing teams to assist in re-entry to the workplace.

<u>Activate Enablers of the Operational Response</u>

Workforce Management

To support the productivity and well-being of the CMS workforce, changes in workforce policy may be required. These adjustments will enable CMS staff to adapt to new challenges arising

from the pandemic and ensure personnel receive the support they need. Examples of workforce policy changes and flexibilities introduced in prior pandemics are detailed below.

Examples from COVID-19 Response
• **Transition to telework** ○ The infectious risk associated with a pandemic may require facilitating a transition to maximize alternate work arrangements. Shifting to a remote working environment may require multiple workforce flexibilities, including: ▪ Expanding the tour of duty for a longer time period, e.g., 5 AM – 11 PM. ▪ Allowing employees to flex out/in or to take unscheduled leave more liberally during working hours due to caregiving responsibilities. ▪ Implementing HHS or Office of Personnel Management (OPM) guidance on flexible leave policies. This may include administrative leave, weather and safety leave, or other leave for CMS employees. ○ FAQs for workforce flexibilities used in the COVID-19 pandemic can be accessed here: FAQs for workforce flexibilities used in the COVID-19 pandemic • **Flexible hiring and onboarding** ○ To maintain normal hiring schedules, CMS can leverage expanded hiring authorities, including Schedule A, Peace Corps, and excepted service authorities. ○ Employee onboarding can be effectively completed in a remote environment by shipping CMS equipment (e.g., laptops, etc.) and establishing virtual trainings and new employee orientation sessions. • **Personnel shifting** ○ As the pandemic may place differential stress on components, CMS can institute flexible systems to allow the reallocation of staff between components to meet surges/demands on given components. ○ Creating a volunteer matching program to assign temporary detailees to areas of high need across the Agency can facilitate personnel shifting. OHC can review volunteer requests to ensure alignment of skills with identified areas of need. • **Employee absenteeism** ○ **NOTE: To be updated with relevant statistics concerning employee absenteeism at conclusion of COVID-19 pandemic.**

Internal Communications

The rapidly evolving nature of a pandemic may require CMS to provide timely and enhanced communication of critical information to staff and managers.

Methods to enhance internal communication include:

- **Developing and Executing An Internal Communications Plan**
  - The Operational response team can draft an internal communications plan focused on achieving three objectives: (1) Sharing gratitude and recognition, (2) Informing and reassuring employees, and (3) Soliciting input from employees.
- **Establishing New and Refined Communications Channels**
  - CMS can create new forums for communication, including pandemic-specific Intranet pages, manager toolkits, and a dedicated email mailbox to provide venues for sharing and collecting communications from staff.

- Employee well-being can be monitored through informal internet polling during All-Staff meetings and through distribution of an employee pulse check survey.

Contracting

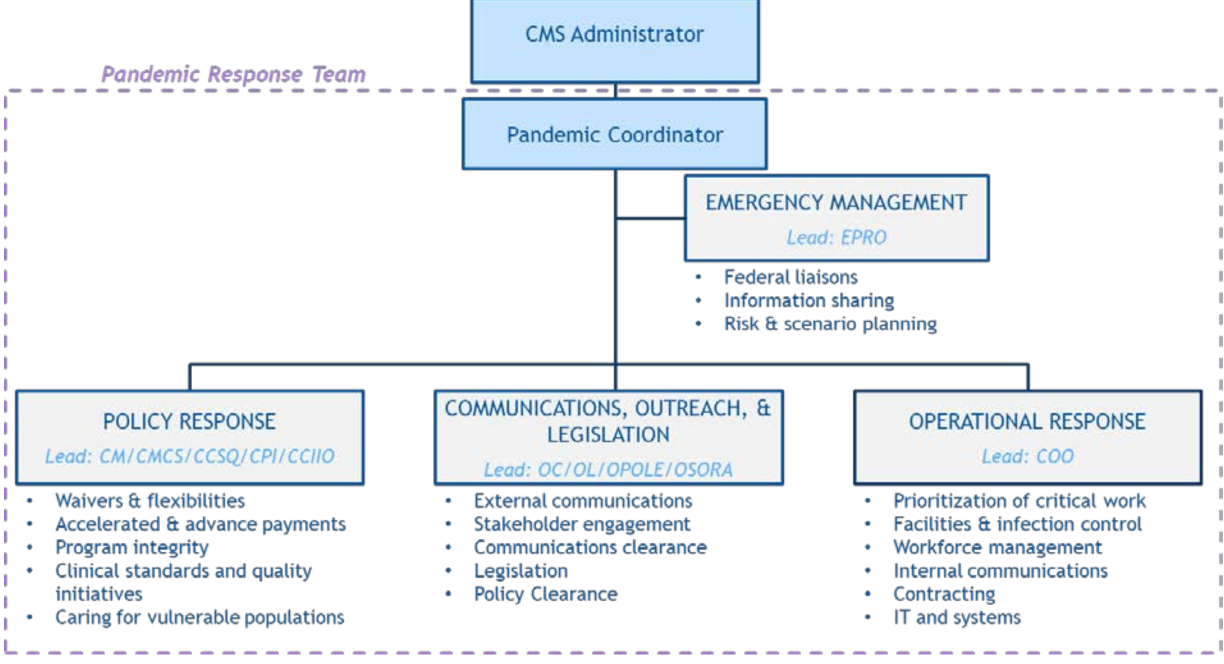
To meet the agency's evolving needs during a pandemic, CMS can leverage contracting and procurement flexibilities arising from the PHE declaration to support the pandemic response. Simplified acquisition thresholds and increased purchase thresholds for PPE and other critical supplies can ensure swift purchasing of inventory as needed and may be used to maintain adequate minimal stockpiles of critical supplies. Contracts may also be modified or paused (see "Prioritization of critical work" above) to repurpose funds for pandemic-related work.

IT and Systems

Information Technology will be important to monitor, analyze, and carry out the Agency's response to the pandemic and to enable staff and vendor partners to adjust to telework. To accomplish this, CMS may need to perform system updates to prepare for potential bandwidth strain that remote work may place on IT systems and to ensure the resiliency of IT platforms, especially those essential to payments. Specific examples include:

- **IT Enhancements** – Oversee necessary system changes (e.g., enable telework and other increased bandwidth capacity and provide monitors and support equipment to teleworkers.
- **Cybersecurity -** Ensure the resilience of IT systems so they can be securely used in a pandemic and probe security risk by testing system penetration (e.g., security testing of HIGLAS payment systems).

7 Direction, Control, and Coordination



7.1 Response Governance Structure and Administration

Figure 3: CMS Pandemic Response Governance Structure

In order to effectively lead CMS' response to the pandemic, CMS will establish a Pandemic Response Team to govern, direct and coordinate the response (see Figure 3 above). The Administrator will appoint a Pandemic Coordinator to spearhead the response team, which consists of four sub-divisions. The function of each element dictates the lead and supporting organizational elements.

The Pandemic Coordinator should be a Director-level or higher senior official with deep domain knowledge of both CMS policy and operations. The Coordinator will be tasked with overseeing the response team, coordinating CMS' response across the entire agency based on the Administrator's guidance, and leading the Pandemic Response Team's meetings.

The Pandemic Response Team is further sub-divided into four main working groups:

- **Emergency Management** –Leads emergency preparation and planning for the organization and guides CMS' collaboration with other federal agencies.
    - Sub-working groups may include: Data analytics group (lead: OEDA and OACT).
- **Policy Response** – Consists of representatives from CM-FFS, CM-C&D, CMCS, CCSQ, CPI, CCIIO, CMS Medical Officers, FCHCO, OMH, and OFM who lead CMS' policy response; the lead for the Policy response group should be a Director or Deputy Director from any

of the above components (depending upon the relevant policy expertise required for the pandemic response).
  - Sub-working groups may include: Pandemic specific survey response group (lead: CCSQ), Clinician group (lead: Chief Medical Officer) and a Provider enrollment group (lead: CPI).

- **Communications, Outreach, & Legislation** – Includes staff from OA, OC, OPOLE, OSORA, and OL who lead communications, engagement with external stakeholders (including local stakeholders), and engagement with the legislative branch and oversight agencies. Sub-group and associated functions may consult with staff from the Centers, Medical Officers, FCHCO, OMH, and OFM for subject matter expertise in engaging with external stakeholders and responding to inquiries.
- **Operational Response** – Led by the Chief Operating Officer and comprised of leaders from CMS' operational components (e.g., OSFLO, OIT, OHC, and OAGM).

In addition to the Agency-level groups, regional office representatives may be designated to coordinate and execute policy and operational actions on the local level. The Pandemic response team will communicate policy and operational decisions to both headquarters (Baltimore and Washington D.C.) and to regional representatives as applicable to keep them situational aware. The exact composition and focus of the response groups may differ during future pandemics. Thus, the framework outlined here should be adapted as needed for future public health emergencies.

7.2 Pandemic Response Team

Emergency Management

The Emergency Management group is principally tasked with guiding emergency planning and response. The group focuses on the collection and sharing of real-time pandemic data to inform the Agency's response and responsibilities within federal incident command. The Emergency management group will provide direct personnel support to the Pandemic Coordinator. Specifically, the functions of Emergency Management include:

- **Information sharing** – Monitors and analyzes CDC, HHS, and FEMA data to assess the impact of the pandemic on local communities and healthcare systems nationally; Creates dashboards for synthesizing and presenting data to CMS leadership (see Section 8: Information Sharing and Scenario Management).
- **Risk & scenario adaptive planning -** Identifies potential pandemic scenarios to proactively develop risk mitigation strategies; Evaluates risks associated with workforce transitions (e.g., re-entry) and facilities workshops to create risk management plans (see Section 8: Information Sharing and Scenario Management).
  - A Medical Officer who is physician or other healthcare professional may be designated to assess the health risk associated with any proposed changes in operations (e.g., re-entry to CMS facilities, etc.) and provide medical approval for operational adjustments that may affect employees' health.

  - The Designated Agency Safety & Health Official (DASHO) who is the designated representative responsible for the safety and health program within CMS or his representative will assess the health risk associated with any proposed changes in operations (e.g. building closure, re-entry to CMS facilities) based on safety and health concerns and make recommendations in accordance with CDC and OSHA requirements.
- **Federal Liaisons** – Serve as link between CMS and federal agencies (e.g., FEMA, ASPR, CDC, etc.); Facilitates pandemic response coordination and provides insight into federal agencies' decision-making; liaisons may be designated for each federal agency involved in the pandemic response and the liaisons will report directly to Pandemic Coordinator (see Section 3.2: National Incident Management System).

Policy Response

The policy response monitors and drafts CMS policy actions in response to the pandemic and may convene additional working groups, sub-working groups, and taskforces as necessary to support these functions. The functions of the group are detailed below to provide an illustrative example of the range of potentially relevant policy issues.

- **Waivers & Flexibilities (leads: CM and CMCS)** – Develops and implements waivers and flexibilities to meet the needs of Medicare, Medicaid and CHIP providers and beneficiaries, and group health plans and health insurance issuers in the group and individual markets and their enrollees, participants, and beneficiaries, making regulatory changes as needed and as authorized in an emergency (see Section 4: Policy response for a detailed explanation of the waiver process and relevant supporting governance bodies, including the Waiver Work Group). It is critical that this group coordinates policy changes across CMS programs to ensure consistent, enterprise-wide response activities for all provider and beneficiary groups.
- **Flexibilities for Health Insurance Issuers Offering Group Or Individual Health Insurance Coverage (lead: CCIIO)** – Provides for relaxed enforcement of certain policies or procedural timeframes in order to remove barriers and provide flexibility for health insurance issuers. CCIIO may also work with the Department of Labor and the Department of the Treasury may provide for flexibilities for group health plans and health insurance issuers offering group or individual health insurance coverage.
- **Clinical standards and quality initiatives (lead: CCSQ)** – Prioritizes federal surveys and determines surveys to suspend for the duration of the PHE, issues guidance on infection control measures in targeted settings, and coordinates infection control and testing guidelines with the CDC and other federal agencies.
- **Caring for vulnerable populations (lead: CCSQ, FCHCO, OMH)** – Issues additional guidance and conducts targeted outreach to support particularly vulnerable populations of beneficiaries who may be adversely impacted by the pandemic.
- **Accelerated and Advance Payments (lead: OFM, CM (assist))** – Expands financial relief programs to aid medical providers including hospital systems and suppliers to increase stakeholders' economic stability.

- **Program integrity (lead: CPI)** – Reviews policy changes to establish safeguards for fraud prevention and prepares documents for audits and oversight activities following the PHE.

Operational Response

The Operational response group leads CMS' internal, operational response to the pandemic. The group monitors day-to-day operations for potential disruptions and provides overarching management for changes in operations during the pandemic. The operational response may be divided into multiple sub-working groups and taskforces based on needs that arise during the pandemic response. The Director or Deputy Director of the components indicated for each function will serve as the point of contact for coordinating each dimension of the operational response. These functions include:

- **Prioritization of Critical Work (lead: COO)** – Allocates resources to ensure prioritized critical business functions are maintained; Initiates the standup and management of the operational response group.
- **Facilities & Internal Infection Control (lead: OSFLO, OPOLE)** – Maintains the safety and security of CMS facilities by implementing infection control procedures (e.g., social distancing, hand hygiene, etc.); Monitors the public health risk at CMS facilities and recommends closure when appropriate; Ensures federal surveyors have access to appropriate PPE; Solicit guidance from the DASHO/CMS Occupational Safety and Health Officer for operational adjustments with the potential to affect employee health. OSFLO and OPOLE will coordinate closely to determine facility status and safety protocols, with OPOLE leading facilities efforts for all regional offices.
- **Workforce Management (lead: OHC)** – Monitors and addresses personnel challenges arising from alternate work arrangements; Ensures continuity in hiring and on-boarding of new staff throughout the pandemic; Facilitates personnel shifting to allow temporary assignment of CMS staff to high need components across the agency.
- **Internal communications (lead: OHC, COO, OC (assist))** – Provides timely updates on changes to CMS workforce policies to agency personnel; Establishes channels to share information and updates with staff and solicit input from employees.
- **Contracting (lead: OAGM)** – Employ contract flexibilities as needed to maintain operations throughout the course of the pandemic.
- **IT and systems (lead: OIT)** – Ensures the security of CMS IT systems and provides equipment and technical support to CMS employees affected by the pandemic.

Communications, Outreach, and Legislation

The Communications and outreach group leads development of external communication materials and interfaces with industry stakeholders and with Congress regarding statutory and regulatory policy during the pandemic. Functions performed by the group include:

- **External communications (lead: OC)** - Prepares external communication messages (e.g., press releases, website updates, etc.) to notify the public of significant CMS actions.

- **Stakeholder engagement (lead: OA)** – Solicits input from industry stakeholders (e.g., providers, nursing homes etc.) to guide CMS policy actions and assess the effect of policy changes.
- **Inquiry response (lead**: **OPOLE, OSORA (assist))** – Establishes help desk and rapid response processes to rapidly triage, track, and address incoming stakeholder inquiries related to the pandemic.
- **Legislation and Congressional Response (lead: OL, OSORA (assist))** – Provides assistance to the Senate and House of Representatives regarding the operationalization and impact of pandemic-related congressional legislation on CMS' programs and to provide timely response to Congressional correspondence and oversight inquiries.

Examples from COVID-19 Response
CMS' governance structure during the COVID-19 response provides guidance on key priorities for establishing a rapid pandemic response structure: ○ CMS created a COVID-19 working group with sub-working groups focused on policy, information management, and intake & outreach. An Internal Operations Center led by the Chief Operating Officer was established to manage changes in CMS day-to-day operations during the pandemic. ○ The guiding principle behind the prior rapid response structure was the union of distinct sub-groups for policy and operational response under a centralized COVID-19 working group. The structure enabled focused discussions and coordination among components principally tasked with executing changes in CMS' operating model and guiding CMS' policy response, respectively. This allowed for the efficient delineation of tasks and responsibilities. ○ The COVID-19 working group brought the sub-groups together via frequent touchpoints at daily meetings and briefing calls between the policy and operational response teams and the Administrator. This approach enabled alignment on CMS-wide priorities and provided visibility into cross-component initiatives during the pandemic.

8 Information Sharing and Scenario Planning

A PHE presents several challenges for CMS leadership. Effective planning for potential policy actions, transitions between pandemic phases, and operational and workforce changes depend on the availability of timely and accurate data. This section details the types of data critical to the agency's response, sources of robust data and lead components responsible for integrating data to inform CMS' preparation and planning for potential scenarios as the pandemic progresses.

Programmatic Data Collection and Analysis

During a pandemic, timely data collection and analysis of the impact on CMS beneficiaries and external stakeholders may be necessary to craft effective waivers and flexibilities to meet stakeholders' needs.

OEDA in collaboration with the Centers and other Offices can support policy decision making by creating and maintaining dashboards of programmatic data (e.g., pandemic related claims data, infection survey data at medical facilities, etc.) for CMS leadership. Consolidating programmatic data in a centralized dashboard can enable a plenary assessment of the adverse impact of the pandemic on beneficiaries and industry stakeholders. OEDA may be tasked with maintaining the dashboard and tailoring the frequency of data release based on the needs of the Policy response. The response groups may aggregate data into a series of reports (or dashboards) to share with the Pandemic response team and the Administrator at daily briefings. Data analysis should stratify by race, ethnicity, dual eligibility for Medicare and Medicaid, disability status, and ESRD status to identify disparities in pandemic impact on vulnerable and minority populations.

Operational Data Tracking and Monitoring

Members of the Operational response group will be responsible for monitoring data metrics relevant to the day-to-day operations of CMS and the well-being of CMS staff. Accurate, contemporaneous data are essential for monitoring the impact of the pandemic and for planning changes in CMS' operations. Potential data to monitor include (but are not limited to):

- Stockpiles and projected demand for PPE and supplies.
- Health of workforce (e.g., infection case count, illness-related absenteeism, etc.).
- Employee sentiment and well-being.
- Employee productivity.
- Offices and centers' personnel status, such as infections and absences due to the pandemic and resultant staffing needs.
- Cybersecurity health and threat incidents.

The group will aggregate and present data via daily dashboard reports for the Administrator to provide continuous assessments of CMS operational needs. Dashboards developed during the COVID-19 response are detailed below.

Examples from COVID-19 Response
• **Programmatic data and dashboards** – OEDA developed dashboards to monitor and analyze CMS programmatic data in a rapidly changing regulatory environment of reporting requirements for CMS providers, beneficiaries, and stakeholders. Programmatic data (shared with the public in dedicated press releases) was stratified by race, ethnicity, disability, dual eligibility for Medicare and Medicaid, and ESRD status to ensure timely awareness of disproportionate impacts of the COVID-19 pandemic on vulnerable and minority populations. • **Pandemic Operations dashboard** – the Internal Operations Center created a consolidated database of high-priority information on the Agency's COVID-19 response in a single Excel dashboard to share with senior leadership. • **Employee roll call bot** – The Office of Support Services and Operations (previously OSSO, now OSFLO) created a bot to track and report employee VPN usage to help the Agency understand and monitor employees' productivity while working from home.

Scenario Planning

Data from multiple sources can be integrated to model hypothetical scenarios and perform contingency planning to mitigate risk to CMS' operations and staff. Proactively preparing and planning for future challenges during a pandemic is critical for minimizing adverse impact to CMS operations and to support policy actions for beneficiaries and external stakeholders.

To accomplish this, CMS may utilize adaptive planning techniques to develop a playbook or series of playbooks for high probability scenarios. The Emergency management group can assess a range of future scenarios (e.g., pandemic duration, infection risk, surge duration, etc.) utilizing CDC data and develop a playbook or series of playbooks to respond to prioritized scenarios. Additionally, the Pandemic Response Team may conduct planning workshops to develop risk mitigation strategies and execution plans for future scenarios.

Information Sharing Among Federal Agencies

To ensure CMS and federal agencies efficiently distribute and share data, the designated liaison(s) (see Section 7: Direction, Control, and Coordination) will be tasked with providing CMS' data on the pandemics' impact on Medicare, Medicaid, and CHIP beneficiaries, enrollees through the Health Insurance Marketplaces®[9], and medical providers with other federal agencies. Similarly, the liaison will gather and consolidate data from FEMA and other federal agencies to share with the Operational response group and the Administrator. The liaison(s) will also share monthly reports on infections and illnesses recorded by CMS staff, the status of CMS' facilities, and other mandated reporting requirements with federal agencies as detailed in CMS' COOP.

External Stakeholder Information Collection

The process and procedures for gathering information from external stakeholders and for responding to stakeholder inquiry requests are detailed in Section 5: Engagement of external stakeholders and Section 4: Policy response, respectively.

[9] Health Insurance Marketplace is a registered service mark of HHS.

Pandemic Data Sources

Several data points on the national impact and scope of the pandemic will be important to guide CMS' response. The table below lists potential sources for relevant data.

Table: Federal data sources

Source	Data
Centers for Disease Control and Prevention	• Infection case count, hospitalizations, and mortality by locality. • Trends in epidemic curve and projected peak infections by HHS region. • School district closures and reopening dates. • Deployments of CDC medical and epidemiological staff by city and state. • Inpatient bed occupancy, ventilator demand, and ICU capacity burden by county and state.
FEMA	• Number of deployed federal medical stations to support local outbreak control. • Quarantine and stay at home orders issued by county and city. • Capacity and number of community-based testing sites by city. • Airport closures and transportation disruptions.
Department of Health and Human Services	• Number of laboratories capable of performing viral testing. • Positive and negative test results by state population. • Inventory of laboratory reagent and testing supplies availability. • Impact of pandemic (e.g., case count) on rural communities [Data may also be available from HRSA, Federal Office of Rural Health Policy, or Department of Agriculture].
World Health Organization	• Infection case count by hospitalizations, and mortality by country.

9 Offices and Centers' Actions By Pandemic Phase

9.1 Readiness and Preparedness (Phase 1B)

During this initial phase, leadership should focus on reviewing existing plans and procedures and disseminating appropriate risk communication messages. As the pandemic progresses into later phases, leadership should continue to take steps to increase the Agency's readiness and preparedness in the event additional incidents occur simultaneously.

Function	Action
Administration and governance	• Identify Component SMEs required for each phase of the pandemic for inclusion in Pandemic response team (all components) • Convene the Pandemic Working Group and determine appropriate meeting cadence for updates (lead: OA) • Monitor and consider recommending suspension of critical yet non-mission essential functions throughout event (lead: OA) • Use task lists and call guides available in EPRO Communications, Coordination, and Continuity Action Team Job Aid to expedite work processes (lead: OA)
Contracting	• Review financial management actions needed to forward fund existing contracts that may have a shortfall to ensure MEF activities continue (e.g., MAC claims processing) (lead: OAGM)
Information sharing	• Gather data on scope of domestic infections and projected extent of the pandemic from CDC (lead: EPRO)
External Communications	• Notify vendor partners and communicate CMS' plans to maintain its MEFs should the pandemic progress into further intervals (all components) • In coordination with HHS, distribute press materials and media outreach to provide the public information on CMS guidance and activities, including direct beneficiary and stakeholder outreach (lead: OC) • Post any relevant PHE declarations on the CMS newsroom and emergency webpages (lead: OC) • Leverage existing Fee-For-Service healthcare providers electronic mail channels to distribute relevant information on pandemic preparations (lead: CM-FFS, OC (assist)) • Leverage existing issuer trade channels to distribute relevant information on pandemic preparations (lead: CCIIO, OC (assist)) • In coordination with OC, provide information on CMS activities to Congressional offices (lead: OL, OC (assist))

Function	Action
Facilities and internal infection control	• Re-familiarize the Pandemic working group and ERG members with alternate work arrangements, to include the COOP Facility, Designated Alternate Sites, and/or social distancing techniques (lead: EPRO) • Ensure health and safety inspections by federal occupational health (FOH) are ongoing (lead: OSFLO). • Begin to procure personal protective equipment (PPE) to ensure stockpiles and distribute PPE to previously identified personnel (lead: CCSQ, OSFLO, OHC (assist))
Internal communications	• Disseminate appropriate risk communication messages to all personnel (lead: OHC, OSFLO (assist))
IT and systems	• Test resilient/redundant communication methods [Government Emergency Telecommunications Service (GETS) card and Wireless Priority Service (WPS)] (lead: OIT)
Stakeholder engagement	• Initiate calls with key stakeholders in impacted states and territories to discuss their readiness/ preparedness plans and provide technical assistance on strategies and actions needed to effectuate them (lead: OC) • Stand up Stakeholder Engagement team to begin coordinating outreach to providers and beneficiaries across all programs (all components)
Survey prioritization and infection control	• Review existing survey work to determine whether actions should be suspended. Work that reviews situations in which entity noncompliance has placed or could place the health and safety of recipients at risk for serious injury, harm, impairment, or death would not be suspended (lead: CCSQ)
Waivers and flexibilities	• Work with FDA and states on any policy issues relating to drug shortages, with respect to managing high demand for an existing or new drug that might treat the pandemic, or interruption in supply chain of drugs due to inability to manufacturer or distribute drugs if the pandemic is centered in a country that supplies APIs or finished dosage forms (lead: OA) • Collect, review, and report on guidance previously issued in similar circumstances, and determine the scope of available waiver authorities that can be implemented in the Part C, Medicare Advantage (MA), and Part D programs (lead: CM - C&D) • Reissue/update memos on requirements flexibilities regarding MA and Part D programs in response to a pandemic (lead: CM - C&D) • Begin providing and posting memos and guidance to state survey agencies to allow flexibility to all provider types (lead: CCSQ)

Function	Action
	• Evaluate need for special enrollment period (SEP), after the declaration of a PHE or under CMS special authority (lead: CM-C&D) • Discuss timelines and triggering events for waiver implementation (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Share standard operating procedures and previously issued waivers for similar situations to determine steps Medicare FFS can begin taking to minimize the impact of the pandemic (CM-FFS)
Workforce management	• Review/implement workforce protection measures (lead: OSFLO) • Review/implement potential procurement/contracts to ensure staffing (lead: OAGM) • Evaluate ERG personnel for workplace and scheduling flexibility (all components) • Identify staff who conduct on-site work (i.e. surveys, interviews) to be provided with appropriate PPE (lead: CCSQ, OSFLO assist)

9.2 Pre-Activation (Phase 1C)

At this phase, confirmed human cases of novel viral infections have occurred in the United States. CMS must take steps to protect the health and wellness of its employees. At this stage of the pandemic progression, activation of the CMS COOP Plan may be imminent, and preparations must be taken to ensure continuity facilities and personnel for the transition of functions and/or personnel away from CMS locations to alternate locations.

Function	Action
Administration and governance	• Provide recommendation to activate the Pandemic Plan and/or CMS COOP Plan. If a recommendation is put forth and accepted, the highest delegated authority approves declaration and activation of the CMS Pandemic Plan (lead: EPRO) • Conduct daily briefing calls with the Administrator and delegate action items to appropriate Components (lead: OA) • If Pandemic response team is convened: o Organize all-hands meetings with the Administrator and conduct daily OA briefings to coordinate CMS' pandemic response across the entire agency (lead: Pandemic Coordinator) o Convene Operational response working group and begin conducting daily meetings to prepare for transition to remote work arrangements (lead: COO) o Establish Communications & outreach group to begin preparing pandemic-specific external communications clearance process (lead: OC, FCHCO (assist), OMH (assist))

Function	Action
	o Provide dedicated personnel to support the Pandemic Coordinator (lead: EPRO) o Establish dedicated internal clearance processes for CMS and non-CMS generated PHE policy documents, and rapid triage/response for PHE correspondence (lead: OSORA) o Identify dedicated Workgroup members to serve as CMS reviewers of PHE policy documents (especially for flash clearances) and points of contact for escalated clearance requests (e.g., PHE workgroup distribution lists) (lead: PHE Coordinator and OSORA)
Contracting	• Components provide necessary oversight and guidance to their vendor partners to ensure corporate pandemic and telework plans remain sustainable (all components) • Components coordinate with their Vendor Partners to ensure CMS minimum physical and cyber security requirements are adhered to during pandemic operations (all components) • Vendor Partners abide by their corporate pandemic and telework plans and ensure plans do not conflict with the contract language and/or CMS mission (all components)
Prioritization of critical work	• Review components' functions and ESAs to identify critical business functions to maintain and functions to pause during the pandemic (all components) • Communicate with Medicare Administrative Contractors (MACs) on contingency plans for potential staff shortages and other strains on resources that could impact their operational performance and ability to meet business critical and mission essential functions (lead: CM-FFS)
External Communications	• Communicate Essential Records information internally and to vendor partners (all components) • Coordinate with HHS to provide guidance that informs risk communications plans and public messaging on the pandemic (lead: OC) • Continue to post relevant waiver updates and guidance to the CMS newsroom and emergency webpages (lead: OC) • If applicable, send a separate notification to subset of impacted states and territories when impact is limited to geographic areas (lead: CMCS) • Provide information on CMS activities to Congressional offices. Notifications may vary by state as needed (lead: OL)
Facilities and internal infection control	• Establish internal team related to exposure risks, potential

Function	Action
	positive cases, and other public health work streams. (OSFLO and OHC) • Engage contact-tracing team and begin case investigations as needed. (OHC) • Evaluate need to defer or cancel large scale events at CMS facilities to prevent the spread of illness (lead: EPRO, OSFLO) • Review HHS/CDC guidance for additional facilities restrictions that may need to be implemented (lead: EPRO, OSFLO) • Evaluate unrestricted use of conference rooms at CMS facilities (lead: OSFLO, OIT) • Verify alternate locations (e.g., COOP facility) (lead: EPRO) • Work with facilities managers and General Services Administration (GSA) to ensure adequate sanitation and hygiene resources are readily available (lead: OSFLO, OPOLE) • Monitor cleaning and sanitation schedules with contractors/GSA to adjust cleaning schedules as needed (lead: OSFLO, OPOLE) • Post signage with reminders of proper hand-washing and cough-covering techniques (lead: OSFLO, OPOLE) • Distribute CMS-provided or supported vaccine(s) (lead: OHC, OPOLE (assist), EPRO) • Deploy additional hand sanitizer/hand washing stations at building entrances, elevators, restrooms, and other high traffic areas (lead: OSFLO, OPOLE) • Increase frequency of cleaning/sanitizing (lead: OSFLO, OPOLE) • Distribute PPE and other risk mitigation materials across all CMS locations as needed (lead: OSFLO, OPOLE, CCSQ) • Implement use of recommended infection control measures in keeping with guidance from public health officials (lead: OSFLO, OPOLE)
Internal communications	• Components update employee contact lists (all components) • Continue dissemination of risk communications material to personnel (lead: OHC, OSFLO, OC (assist)) • Develop additional messaging as needed, to include: steps CMS is taking to mitigate the spread of illness, personnel relocation plans, telework actions, and workforce flexibilities (pay, hiring, leave options, OPM guidance, requirements, etc.) (lead: OHC, OC (assist)) • Coordinate HHS approved risk communications, messaging, and dissemination with the Agency (lead: OC)
IT and systems	• Coordinate with Office of Information Technology (OIT) to send a

Function	Action
	broadcast message link to all CMS personnel in the Emergency Notification System to update emergency contact information (lead: OHC) • ERG, DERG, and continuity personnel take laptops and essential work-related materials home daily (all components) • Should CMS institute telework across the agency to prevent illness, examination and consideration must be made for onsite vendor partners through CMS and contract oversight (all components) • Prepare for the full utilization of remote access capabilities and ensure the availability and redundancy of essential records and critical systems (lead: OIT)
Legislation	• Work with Congress to ensure needed statutory authorities reflect current requirements. Provide assistance to Committees of jurisdiction and individual Members of Congress as they consider legislation affecting CMS programs to address the emergency. (lead: OL)
Stakeholder engagement	• Coordinate national and targeted beneficiary communications, messaging, and timing in close coordination with HHS as appropriate (lead: OC, OMH, FCHCO) • Begin outreach to states, providers, issuers, and beneficiary advocacy groups, including organizations that serve vulnerable populations (lead: OC, CM (assist), CMCS (assist), OMH (assist), FCHCO (assist), CCIIO (assist)) • Develop communications to state Medicaid and CHIP agencies, about CMS activities (lead: OC, CMCS (assist)) • Initiate/Facilitate calls between the Administrator and Congressional leaders about the Agency's plans/response (lead: OL) • Provide information on CMS activities to Congressional offices. Notifications may vary by state as needed (lead: OL) • Resolve incoming questions and casework from Members of Congress (lead: OL) • Respond to and coordinate stakeholder meeting requests for the Administrator (lead: OSORA)
Waivers and flexibilities	• Review repository of waivers and flexibilities issued in prior pandemics (e.g., COVID-19 policy repository) to determine if any blanket waivers or state Medicaid flexibilities should be implemented (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Compile guidance issued in prior pandemics to accompany

Function	Action
	waivers and flexibilities and begin updating (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Set up communications liaison to ensure linkage with critical partners to include capture of any clearance requirements, including coordination with the CDC to ensure appropriate ICD-10-CM Diagnosis Code is in place or in development (lead: CM-FFS)
Workforce management	• Verify personnel telework agreements within respective Components (all components) • Managers evaluate alternating shift work schedules (all components) • Division managers develop and communicate steps to subordinates for purposes of orders of succession (all components) • Implement daily and weekly reporting (all components): o Division managers provide daily personnel status to Group Directors. Group Directors relay personnel data to Components Directors, or designee, according to Division protocols o Components send weekly personnel accountability to OHC • Establish exception reporting for all components to identify affected personnel, as well as general absenteeism. ITAS reporting should be leveraged (lead: OHC)

9.3 Activation (Phase 2A)

When cases of the novel infection are confirmed and have demonstrated efficient human-to-human transmission, anywhere in the world, the initiation of a pandemic wave has begun. Accordingly, the CDC Initiation Interval is set in motion.

Function	Action
Administration and governance	• Increase frequency daily briefing calls with the Administrator (lead: Pandemic Response Team) • Continue twice daily briefing calls with the Pandemic coordinator (lead: EPRO)
Accelerated and Advanced Payments	• Expand existing Accelerated and Advance Payment programs to Medicare Part A providers and Part B suppliers nationwide (lead: OFM, CM (assist))
Contracting	• Review and implement applicable procurement and contracting flexibilities using relevant sections of the FAR (lead: OAGM)

Function	Action
External Communications	• Update and provide new risk messaging (including National Provider Identifiers) and update guidance for detection, diagnosis, and treatment (lead: CM - FFS, OC (assist)) • Coordinate with the CMS Call Center and Media Relation Teams to prepare for high volume of public and media inquiries (lead: OC) • Convene workgroup of CMS policy staff to coordinate distribution of press releases to externally-facing listservs of providers, issuers, and beneficiaries (lead: OC, CM (assist), CMCS (assist), CCIIO (assist)) • Deploy dedicated clearance processes for CMS-generated policy documents and clearance of non-CMS generated clearance requests (lead: OSORA) • Initiate/Facilitate calls between the Administrator and Congressional leaders about the Agency's plans/response (lead: OL) • Provide information on CMS activities to Congressional offices. Notifications may vary by state as needed (lead: OL) • Resolve incoming questions and casework from Members of Congress (lead: OL) • Issue information/guidance to MA and Part D Sponsors on requirements and available flexibilities in the MA and Update and Part D programs in response to a pandemic (lead: CM-C&D) • CMS clinicians establish and maintain ongoing communication channels with key stakeholders to address the evolution of the pandemic in their respective regions and obtain feedback on potential strategies for CMS to provide assistance. (lead: CCSQ)

Facilities and internal infection control	• Continue increased frequency for janitorial and sanitary practices (lead: OSFLO, OPOLE)
	• Coordinate with General Services Administration and Program Support Center (PSC) on janitorial service provision to (lead: OSFLO, OPOLE):
	    o Ensure adequate sanitary supplies of PPE and other infection control measures are available in high traffic areas
	    o Enforce sanitary water and food cooking and distribution practices
	    o Ensure the continuation of critical infrastructure services (e.g., power, sanitation, and water)
	• Encourage use of video teleconferencing, WebEx, WebEx Teams, and Skype as alternatives to conference rooms. No mandatory

Function	Action
	restrictions on use of conference rooms are expected at this time. (lead: OIT) • Update recommended infectious disease control measures (lead: OSFLO) • Implement and monitor vaccine distribution as appropriate (lead: EPRO) • Implement use of recommended infection control measures in keeping with guidance from public health officials (lead: OSFLO, OPOLE, EPRO (assist)) • Encourage self-isolation, staying home, of personnel who are sick (lead: OSFLO, OHC) • Consider recommending staff avoid public forms of transportation and mass gatherings (lead: OSFLO) • Implement any appropriate health surveillance and monitoring plans or procedures, including health screenings, to assess employees' physical health and fitness to attend work (lead: EPRO, OHC (assist)) • Assess the health risk to CMS' workforce associated with any proposed changes in operations and provide medical approval for operational adjustments that may affect employees' health (lead: EPRO)
Internal communications	• Disseminate updated HHS approved risk communications to CMS staff (lead: OC) • Share information on Employee Assistance Program services available to CMS personnel (lead: OHC) • Communicate regular continuity updates through appropriate CMS conference calls (lead: Pandemic response team) • Collaborate with the Centers and other Offices to support policy decision making by creating and maintaining dashboards of programmatic data (e.g., pandemic related claims data, infection survey data at medical facilities, enrollment data, etc.) (lead: OEDA)
Legislation	• Work with Congress to ensure needed statutory authorities reflect current requirements. Provide assistance to Committees of jurisdiction and individual Members of Congress as they consider legislation affecting CMS programs to address the emergency (lead: OL)
Liaison	• Establish link with FEMA, ASPR, or other Agencies as needed to coordinate pandemic response planning (lead: Pandemic Response Team)

Function	Action
Risk and scenario planning	• Engage in scenario and risk planning to analyze current/projected ability to support MEFs (lead: EPRO)
Stakeholder engagement	• Provide healthcare providers, emergency medical services (EMS), hospitals, healthcare associations, issuers, and other medical treatment facilities, technical assistance and guidance on resource allocation, care protocols, and alternate care facilities as needed (lead: CM, CMCS, CCIIO) • Evaluate opportunities to engage beneficiaries and beneficiary advocacy groups in outreach calls (lead: FCHCO, OMH) • Continue calls with impacted states and territories to assess their needs and obtain status updates (lead: CMCS) • Continue calls with impacted issuers and states to assess their needs and obtain status updates (lead: CCIIO) • Establish help desk to triage and process stakeholder inquiries (lead: OPOLE) • Coordinate with OPOLE to establish process for CMS SMEs to review and respond to written correspondence (lead: OSORA) • Stand up toll-free hotlines to answer providers' questions and enroll in CMS programs (lead: CM)
Survey prioritization and infection control	• Partner with OSFLO to validate that staff have the appropriate medical clearances, been fit tested, and have the appropriate PPE to deploy to survey medical facilities (lead: CCSQ)
Waivers and flexibilities	• Implement waivers and other legal flexibilities identified within Medicare Advantage and Part D program rules to ensure continuity of coverage and access for beneficiaries (lead: CM – C&D) • Post blanket waivers cleared by CMS leadership and the Office of General Counsel (OGC) to CMS.gov and release to providers for educational and informational purposes (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Evaluate and respond to individual waiver requests submitted by providers (lead: CCSQ) • Issue special certifications or approvals to providers to use alternative settings (e.g., special purpose facilities, temporary structures) to maintain and increase capacity (lead: CCSQ) • Review and respond to state requests for state-specific, Medicaid and CHIP waivers and flexibilities. (lead: CMCS)
Workforce management	• Evaluate need to shift work between groups/offices due to infection rates (all components) • Report any positive cases or staff deaths immediately though the

Function	Action

	supervisory chain to CMS Senior Leadership (all components)
	• Twice per week reporting (start of the week and end of the week) (all components):
	  o Division managers provide daily personnel status to Group directors. Group directors relay personnel status to Components following internal processes.
	  o CMS Components send personnel accountability information to OHC.
	• Provide CMS staff with frequent updates on workplace flexibilities, telework, and changes in human capital policies (lead: OHC)
	• Establish re-assignment program to allocate personnel to high-stress components and detailees (lead: OHC)
	• Monitor and evaluate impact of potential public transportation disruptions (lead: OSFLO)
	• Reports personnel status from Components to EPRO (lead: OHC)

9.4 Operations (Phases 2B – 2C)

As CDC heightens its pandemic response, advancing to the Acceleration Interval, the United States Government is likely to instruct all levels of government to activate any applicable pandemic plans.

Function	Action

Administration and governance	• If the COOP Plan is activated (all components):
	  o Implement ERG accountability and relocation measures, in accordance with the CMS COOP Plan.
	  o Implement non-ERG accountability measures, in accordance with the CMS COOP Plan.
	• Continue twice-daily briefing calls with the Administrator (lead: EPRO)

External Communications	• Issue press releases and update CMS website to keep beneficiaries and providers updated on status of CMS services (e.g., call centers, coverage) (lead: OC) • Initiate/Facilitate calls between the Administrator and Congressional leaders about the Agency's plans/response (lead: OL) • Provide information on CMS activities to Congressional offices. Notifications may vary by state as needed (lead: OL) • Resolve incoming questions and casework from Members of Congress (lead: OL)

Function	Action
Facilities and infection control	• Implement appropriate public health measures, including social distancing recommendations and applicable workforce policies (lead: OHC and OSFLO) • Close affected CMS facilities if needed and confirm telework protocols (lead: OSFLO, OPOLE) • Restrict conference room usage and enforce alternate meeting tools; video teleconferencing, WebEx, WebEx Teams, and Skype only (lead: OSFLO, OIT) • Implement use of recommended PPE and other infection control measures in keeping with guidance from public health officials (lead: OSFLO) • Implement appropriate health surveillance and monitoring plans or procedures, including health screenings, to assess employees' physical health and fitness to attend work (lead: OHC)
Internal communications	• Disseminate updated risk messaging to CMS staff (lead: OHC) • Notify Components of any strategic or priority changes as the situation dictates (lead: Pandemic Response Team)
Legislation	• Work with Congress to ensure needed statutory authorities reflect current requirements. Provide assistance to Committees of jurisdiction and individual Members of Congress as they consider legislation affecting CMS programs to address the emergency (lead: OL)
Stakeholder engagement	• Increase external outreach to beneficiaries, stakeholders, and media (lead: OC, OPOLE, FCHCO, OMH)
Accelerated and Advance Payments	• Administer Accelerated and Advance Payments programs (lead: OFM, CM (assist))
Waivers and flexibilities	• Monitor efficacy of issued waivers and legal flexibilities of Medicare Advantage and Part D program rules to ensure continuity of coverage and access for beneficiaries (CM – C&D) • Respond to stakeholder questions and monitor the efficacy of the implemented waivers (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Implement additional blanket and individual waivers if necessary and legally permissible (lead: CM, CMCS, CCSQ, CPI, CCIIO)
Workforce management	• Division managers continue to provide personnel status and communicate to leadership (all components) • Components provide twice daily (a.m. and COB) situation report to leadership with any critical do outs, need to knows (numbers of sick employees, overall staffing needs, serious issues, etc.) (all components) • Report any positive cases or staff deaths immediately though

Function	Action
	your supervisory chain to the Operational response group (all components) • Identify workforce gaps and provide operational status to EPRO (all components) • Mandatory daily check-ins by component/group for employee monitoring led by managerial/supervisory staff (all components) • Communicate and implement mandatory telework, and other workplace flexibilities, e.g., extended tour of duty, administrative leave, etc. (lead: OHC) • Identify and report positive cases and personnel quarantined in any location, including their home, to the established exception reporting metrics (lead: OHC)

9.5 Reconstitution

The primary challenge for CMS as a pandemic wave decelerates will be preparation for subsequent waves and the replacement of personnel unable to return to work. As the CMS Reconstitution Lead, OHC will communicate any Department-wide guidance on the process of personnel returning to their normal duty stations.

Function	Action
Administration and governance	• Hold daily briefing calls with Administrator as needed (lead: Pandemic Response Team) • Evaluate ongoing need for Pandemic response team and dissolve response structure once the pandemic threat subsides (lead: OA) • Conduct After-Action briefing and prepare the After-Action Report (AAR). Corrective action items are identified and assigned to appropriate Components and integrated into future planning efforts. (lead: EPRO)
Accelerated and Advance Payments	• Reevaluate the Accelerated Payment Program and discontinue the Advance Payments programs over a phased period (lead: OFM, CM (assist))
External Communications	• Communicate CMS operational status to the public (e.g., reopened facilities, services, etc.) (lead: OC) • Initiate/Facilitate calls between Administrator and Congressional leaders about the Agency's response or needed legislation (lead: OL) • Resolve incoming questions and casework from Members of Congress (lead: OL)

Function	Action
	HHS and recommended by the CDC and OSHA, to return to steady state operations (lead: OSFLO, OPOLE) • Reduce restrictions on conference room use; continue to encourage use of video teleconferencing, WebEx, WebEx Teams, and Skype (lead: OSFLO, OIT)
Legislation	• Work with Congress to ensure needed statutory authorities reflect current requirements. Provide assistance to Committees of jurisdiction and individual Members as they consider legislation affecting CMS programs to address the emergency. (lead: OL)
Risk and scenario planning	• Prepare for subsequent waves of the pandemic, building on lessons learned from the pre-activation and operational phases (lead: EPRO) • Communicate lessons learned and recommendations to enhance preparedness for subsequent waves of the pandemic to the Pandemic Coordinator (lead: EPRO) • Identify Corrective action items from AAR and assign tasks to appropriate Components for integration into future planning efforts (lead: EPRO)
Survey prioritization and infection control	• Resume survey activities paused during the pandemic event. (lead: CCSQ) • Provide personal health and safety guidance to personnel returning to survey field work (lead: CCSQ)
Waivers and flexibilities	• Assess activities impacted by the pandemic and determine which, if any, waivers and flexibilities approved during the pandemic may be made permanent and how others should be rolled back (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Begin collecting and analyzing data on the impact of approved waivers and flexibilities (lead: CM, CMCS, CCSQ, CPI, CCIIO) • Review and communicate permanency of MA and Part D flexibilities to return to "business-as-usual" (lead: CM-C&D) • Coordinate with the CDC to ensure appropriate ICD-10-CM Diagnosis Code is in place or in development (lead: CM-FFS) • Develop and issue policy guidance to state Medicaid and CHIP agencies providing direction on how they should "unwind" approved waivers and flexibilities and return to normal operations (lead: CMCS)
Workforce management	• Continue to provide updates on positive cases and personnel status including personnel returning to duty stations and continued telework dependencies (all components)

Function	Action
	• Report personnel status to EPRO and CMS Senior Leadership (lead: OHC) • Assess sufficiency of resources to commence reconstitution efforts (lead: OHC and OSFLO) • Coordinate with HHS and OPM on the implementation of procedures to assess staff shortages and accelerate hiring to fill workforce gaps, as needed (lead: OHC) • Activate process for recovered/well staff members to return to work (lead: OHC) • Establish Re-Entry team to develop a formal plan and phased approach to gradual return to the workplace (lead: OHC, OPOLE) • Coordinate with HHS and other Operating Divisions to increase consistency of re-entry information provided to CMS staff (lead: OHC) • Instruct personnel to return to regular duty stations as situation allows (lead: OSFLO, OHC) • Continue physical health monitoring and provide mental health services, along with post-trauma awareness training (lead: OHC) • Prepare facilities, public health policies, personnel screening and safety protocols to support an increase in on-site employee presence (lead: OSFLO)

10 Plan Development and Maintenance

The pandemic plan should undergo routine updates at a minimum of every year to reflect changes in CMS operations, evolving statutory and regulatory guidelines, and alterations in the policy approval process. Refreshes to the pandemic plan should also occur following major public health emergencies.

Following a return to normal operations after a pandemic or other relevant PHE, EPRO should conduct appropriate post-pandemic activities, including hot washes, or immediate discussions and evaluations of an agency's performance following an exercise, training session, or major event and more in-depth after-action conferences. This will enable EPRO to gather qualitative and quantitative results from the Agency’s response to the pandemic and to identify areas for improvement. All opportunities for improvement will be captured and synthesized into a continuity Corrective Action Plan.

ANNEX A – Acronyms and Abbreviations

ACRONYM	TRANSLATION
AAR	After Action Report
ASPA	Assistant Secretary for Public Affairs
ASPR	Assistant Secretary for Preparedness and Response
AV	Antiviral
BCP	Business Continuity Plan
CCIIO	Center for Consumer Information and Insurance Oversight
CCSQ	Center for Clinical Standards and Quality
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CLIA	Clinical Laboratory Improvement Amendments
CMCS	Center for Medicaid and CHIP Services
CM-FFS	Center for Medicare Fee-For-Service
CM-C&D	Center for Medicare Parts C & D
COOP	Continuity of Operations
DASHO	Designated Agency Safety and Health Official
DERG	Devolution Emergency Response Group
DHS	Department of Homeland Security
DME	Durable Medical Equipment
DPC	Domestic Policy Council
EOP	Emergency Operations Plan
ENS	Emergency Notification System
EPRO	Emergency Preparedness & Response Operations
ERG	Emergency Relocation Group
FCHCO	Federal Coordinated Health Care Office
FOH	Federal Occupational Health
FSLTT	Federal, State, Local, Tribal, and Territorial
GETS	Government Emergency Telecommunications Service
GSA	General Services Administration
HHS	U.S. Department of Health and Human Services
HIGLAS	Healthcare Integrated General Ledger Accounting System
HRSA	Health Resources and services Administration
ITAS	Integrated Time and Attendance System
MEFs	Mission Essential Functions
MERS	Middle East Respiratory Syndrome
NPI	National Provider Identifier
OA	Office of the Administrator
OACT	Office of the Actuary

OC	Office of Communications
OGC	Office of General Counsel
OHC	Office of Human Capital
OIT	Office of Information Technology
OIRA	Office of Information and Regulatory Affairs
OL	Office of Legislation
OMH	Office of Minority Health
OPM	Office of Personnel Management
OPOLE	Office of Program Operations and Local Engagement
OSFLO	Office of Security, Facilities, and Logistics Operations
OSHA	Occupational Safety and Health Administration
OSORA	Office of Strategic Operations and Regulatory Affairs
PHE	Public Health Emergency
POC	Point of Contact
PPE	Personal Protective Equipment
PSC	Program Support Center
PTAN	Provider Transaction Access Number
SARS	Severe Acute Respiratory Syndrome
SME	Subject Matter Expert
SOP	Standard Operating Procedures
WHO	World Health Organization
WPS	Wireless Priority Service

ANNEX B – Definitions

Term	Meaning
Antiviral Chemoprophylaxis	Antiviral chemoprophylaxis is the use of antiviral drugs to prevent illness. Antiviral chemoprophylaxis is often used in response to outbreaks in nursing homes or other types of facilities that care for residents at high risk of disease complications, to prevent spread of disease.
Antivirals	Prescription medicines (pills, liquid, an inhaled powder, or an intravenous solution) that fight against viruses in the body. Antiviral drugs are different from antibiotics, which fight against bacterial infections.
Asymptomatic	Without symptoms. The presence of, or suspected presence of, an infection without symptoms. Also known as an apparent infection or subclinical infection.
Attack Rate	The risk of getting the disease during a specified period, such as the duration of an outbreak. Calculated as the number of new cases of disease within a defined population during specified time interval divided by the population at the start of the time interval.
Basic Reproduction Number (R_0)	The basic reproduction number of an infection can be thought of as the expected number of cases directly generated by one case in a population where all individuals are susceptible to infection. Pronounced “R naught.”
Coronavirus	Coronaviruses cause a number of respiratory infections in humans, mild viruses including the common cold, as well as rarer strains such as SARS, MERS, and the recent emergence of the novel COVID- 19 virus. Transmission of coronaviruses occurs through close contact with respiratory droplets from sneezing and coughing.
Endemic	The constant presence of a disease or infectious agent within a given geographic area or population group; may also refer to the usual prevalence of a given disease within such area or group.
Epidemic	The occurrence of more cases of disease than expected in a given area or among a specific group of people over a particular period of time.
Flexibility	A sub-regulatory change to broaden or loosen Medicare, Medicaid, CHIP or CCIIO policy requirements.
Hot Wash	The immediate discussions and evaluations of an agency's performance following an exercise, training session, or major event. Corrective action items may be identified and assigned to appropriate stakeholders to integrate into future planning efforts.
Incubation Period	The time from contact with infectious agents (bacteria or viruses) to onset of disease.
Influenza	There are four types of influenza viruses: A, B, C and D. Human influenza A and B viruses cause seasonal epidemics of disease (known as the flu season) almost every winter in the United States. Influenza A viruses are the only influenza viruses known to cause flu pandemics, i.e., global epidemics of flu disease.
Isolation	The separation of sick persons from the rest of the population.

Term	Meaning
Pandemic	An epidemic occurring over a very wide area (several countries or continents) and usually affecting a large proportion of the population.
Pathogens	Organisms (e.g., bacteria, viruses, parasites, and fungi) that cause disease in human beings.
Presymptomatic	Infected but before the onset of recognized symptoms.
Quarantine	The isolation of a person who been exposed to a disease, but not known to be infected, in order to prevent further spread of the disease.
Regulatory	Relating to rules established by executive branch agencies to carry out statutory responsibilities, policies established by regulation can be revised consistent with the discretion afforded to the federal agency without Congressional approval.
Statutory	Pertaining to a law or provision established by an act of congress (i.e. statute); policies created by statute require an act of Congress to modify.
Super-spreader	A minority of individuals who infect disproportionately more susceptible contacts, as compared to most individuals who infect few or no others.
Tour of Duty	The tour of duty defines the limits within which an employee must complete his or her basic work requirement. (as stated in the CMS 2017 Master Labor Agreement)
Vendor Partners	Contractors that work in partnership with the Agency and its partners.
Viral Shedding	The release of virus from the host. In some cases, infected individuals may shed viruses before showing symptoms and after resolution of symptoms.
Virus	A tiny organism, smaller than a bacterium, that multiplies within cells and causes disease such as chickenpox, measles, mumps, rubella, pertussis and hepatitis. Antibiotics, the drugs used to kill bacteria, do not affect viruses.
Waiver	Temporary suspension or modification of certain Medicare, Medicaid, CHIP or HIPAA statutory or regulatory requirements; Typically done pursuant to a statute giving the Secretary the discretion to waive certain requirements if conditions are met or granted pursuant to specific authority set out in an existing statute or regulation.
Warm Site	A facility used to recover an agency’s operations and/or technology infrastructure when its primary operations and/or data center goes down. A warm site features an equipped operations space and/or data center.

ANNEX K – Strategic Planning Framework for the Center for Medicaid and CHIP Services

PLANNING FOR A PUBLIC HEALTH EMERGENCY OR NATURAL DISASTER

Medicaid and the Children's Health Insurance Program (CHIP) play an important role in ensuring essential health care services for more than 76.4 million Americans, including 37 million children as of August 2020. As a critical part of our nation's health care safety net, these programs must be especially adaptive and responsive in times of emergencies—natural and human-made disasters, epidemics, and other emergencies.

The Center for Medicaid and CHIP Services (CMCS) developed this Strategic Planning Framework as a resource for CMCS leadership and staff to consult when there are Public Health Emergencies (PHEs), natural disasters and other emergencies (referred to collectively throughout as "emergencies"). The Strategic Planning Framework is organized into eight discrete steps to guide a response. When emergencies arise, the CMCS leadership team should think through these eight steps and act on them. These actions focus more heavily on CMCS's internal organizational response and its work with state Medicaid and CHIP agencies rather than CMCS's role as an employer, because CMCS follows the agency's direction in that area. The steps that CMCS would take in assessing different types of emergencies are the same, yet the responses vary based on the size and scope of the emergency.

Strategic Planning Framework Summary

This section describes a strategic framework for CMCS's response to an emergency, as summarized in Table 1-1, with more detail on each action step.

Table 1-1: Strategic Planning Framework for Emergency Response

ACTION/Step	DESCRIPTION
1. Establish leadership team, and conduct situational awareness of the emergency	At the onset of any emergency, establishing a leadership team is critical to operationalizing and coordinating CMCS's response. The leadership team will need to develop processes for decision-making, coordinating, and tracking the response. The team will need to assess the nature and scope of the emergency to shape the CMCS response and identify the impact of the crisis on state Medicaid and CHIP operations, Medicaid and CHIP applicants and beneficiaries, and CMCS staff and operations.

ACTION/Step	DESCRIPTION
2. Assess state Medicaid and CHIP agency operations and needed flexibilities	CMCS should seek to understand the impact of the crisis on states' ability to execute their regular daily operations and serve Medicaid/CHIP beneficiaries, applicants, providers, and other key stakeholders. This should include the capacity of state agency workforce and offices, IT system functionality, states' ability to conduct essential operations, and state staff's ability to communicate with one another and with CMS. Based on this assessment, consider the flexibilities that may be needed for state Medicaid and CHIP agencies to operate effectively and efficiently throughout the emergency. These flexibilities could include authorities available under section 1135 waivers, section 1115(a) demonstrations, the Medicaid and CHIP state plan, Home and Community-Based Services (HCBS) Appendix K, emergency IT funding, and existing regulatory flexibility. Determine whether existing authorities and flexibilities are sufficient or whether new provisions or strategies will need to be pursued.
3. Assess impact on health care delivery system	Based on information from state Medicaid and CHIP agencies, provider groups, and other key stakeholders, assess the impact of the emergency on providers and identify accommodations that are necessary to ensure that a robust workforce and necessary supplies are available to deliver health care services during the period of the crisis. CMCS may also want to consider various mechanisms/strategies to allow states to address payment methodologies and leverage managed care flexibilities, including modifications to managed care contracts and rates. CMCS will need to coordinate closely with broader CMS efforts to support providers and health care delivery systems. Many section 1135 waivers and other flexibilities needed are under the purview of other agency components, including the Center for Medicare (CM) and the Center for Clinical Standards and Quality (CCSQ).
4. Establish CMCS organizational response structure	Consider how CMCS needs to staff the response, including through the creation of teams and temporary shifts in work assignments. The need for organizational changes will depend on the size and scope of the emergency.
5. Establish communication strategies	Initiate emergency-related communications with: • Other parts of CMS, including the Office of the Administrator, the Emergency Preparedness and Response Operations Office, and other CMS components (CM and CCSQ) for certain Medicare section 1135 waiver flexibilities that can be used by Medicaid programs • CMCS staff • State Medicaid and CHIP agencies • Key stakeholder groups

ACTION/Step	DESCRIPTION
6. Establish a technical assistance strategy to support state Medicaid and CHIP agencies	Initiate calls with state Medicaid and CHIP agencies to assess their needs. Based on feedback from the initial calls, develop a strategy to provide TA on particular policies, waivers, and flexibilities. The strategy should consider the appropriate forum to provide technical assistance (TA), including all-state calls, and issuance of written guidance such as frequently asked questions, CMCS Informational Bulletins, State Health Official letters, or State Medicaid Director letters. TA will also include use of tools and checklists that streamline the process for the submission, review, and approval of state requests.
7. Establish mechanisms for tracking and monitoring	Review existing tools in place to capture real-time feedback and adjust the implementation plan as needs evolve on the ground.
8. Deploy strategies needed to support CMCS operations and staff affected by the emergency	Assess the impact of the emergency on CMCS operations and the staff's ability to carry out their responsibilities. Coordinate closely with CMS's Office of the Administrator, Office of the Chief Operating Officer, Office of Human Capital, and Office of Information Technology.

Step 1: Establish Leadership Team, and Conduct Situational Awareness of the Emergency

At the onset of any emergency, it is critical to establish a leadership team expediently to operationalize and coordinate CMCS's response. The leadership team will need to institute processes for decision-making, coordinating, and tracking the response and determine how to prioritize or coordinate these tasks with ongoing duties of CMCS. Leadership should define clear lines of accountability to ensure agency leadership, CMCS staff, states, and coordinating federal agencies understand the appropriate contacts for decisions, processes, and questions. The size of the leadership team should be dictated by the scope and scale of the emergency and could range from a single person to a large team, depending on the areas of authority within CMCS that are needed as part of the emergency response.

The leadership team will assess the scope and scale of the emergency and identify the impact of the crisis on state Medicaid and CHIP operations, Medicaid and CHIP applicants and beneficiaries, and CMCS staff and operations to shape and appropriately scale the CMCS response. The team needs to understand whether the emergency is man-made or naturally occurring, and if it's a naturally occurring, whether it is disease-based, weather-related or something else. If the emergency is a declared PHE or a pandemic, the CMCS team will need to work with agency leadership to follow guidance from national experts and align with the CMS Pandemic Plan. As part of situational awareness, the leadership team should monitor and assess the stages of the emergency to determine the appropriate response as it evolves (e.g., a pandemic response should calibrate the response to pre-pandemic, acceleration, and deceleration phases).

The factors listed in **Table 1-2** can be used to assess the scale and scope of an emergency. Each step in this strategic planning framework will require consideration of these specific scale and scope factors.

Table 1-2: Key Factors to Assess the Scope and Scale of an Emergency

SCOPE AND SCALE FACTOR	DESCRIPTION
Geography	Considerations include the geography of the emergency—whether it is nationwide or affects an entire state, is concentrated in one or more geographic regions (e.g., border states), or affects urban and rural areas.
Impacted populations	Considerations include the number of people affected by the emergency, what is known about the impact on the population, and what population subsets are affected (children, older adults, people with disabilities, racial or ethnic groups).
Expected duration	Considerations include identifying what is known about how long the emergency will last (days, weeks, months) and the long-term impact.
Public infrastructure	Considerations include whether utilities are functional (e.g., electricity, water, internet, heating), the impact on transportation and structures including homes and businesses, as well as whether individuals have been displaced and, if so, whether they are in state or moved out of state.
State and local government staff and operations impact	Considerations include whether state and local government offices are open and operating, the capacity of state agency staff, implementation of telework at the state level, whether state or local command centers have been established, whether communicating with state officials is possible if normal operations have been interrupted, and impact on essential operations at the state level (eligibility operations, claims payment, drawing down funds from CMS and associated IT systems).
CMCS staff and operations impact	In coordination with Office of the Administrator (OA), the Chief Operating Officer, and the Office of Human Capital, leadership needs to assess CMCS and agency operations, including IT systems and essential operations. For CMCS staff, considerations include whether they are directly affected or reduced, personal injury or illness, loss of staff's homes, childcare, school closings, transportation, and ability to telework.

Step 2: Assess State Medicaid and CHIP Agency Operations and Needed Flexibilities

CMCS should assess the impact of an emergency on states' ability to execute normal operations and serve Medicaid and CHIP beneficiaries and providers. This type of assessment is a crucial step to ensure that CMCS has the necessary information to make appropriate decisions about the types of flexibilities that may need to be requested by state Medicaid and CHIP agencies. The flexibilities that are requested and approved through the range of authorities available will contribute to ensuring both continuity of care for beneficiaries and payment for providers throughout the emergency, as well as the ability for individuals at apply for and retain coverage through Medicaid and CHIP. CMCS should engage with state Medicaid and CHIP agencies to (1) gather information for use in the assessment and (2) pressure test preliminary conclusions drawn from the information gathered from the state and from any available independent sources to ensure CMCS is operating with the most accurate and relevant information.

CMCS Approach to Needed Authorities and Flexibilities

Based on information provided by the assessment outlined above, the CMCS team would then consider the authorities and flexibilities that may need to be requested by state Medicaid and CHIP agencies and approved by CMS to operate effectively and efficiently throughout the emergency. Existing regulatory flexibility should also be considered.

CMCS should engage with state Medicaid and CHIP agencies as it considers the range of authorities and flexibilities that may be available, appropriate, and useful based on the scope and scale of the emergency. The importance of ongoing dialogue between CMCS and state Medicaid and CHIP agencies to determine the authorities and flexibilities that are desired and necessary cannot be overstated. The CMCS team should determine whether existing authorities and flexibilities are sufficient or whether approval of new ones will be required.

EXAMPLES FROM PREVIOUS EMERGENCY RESPONSES

For smaller-scale emergencies, such as those declared in Florida in response to Hurricane Irma, Florida Medicaid and CHIP agencies were operational but beneficiaries were evacuated and relocated to other states. As a result, Florida needed a streamlined process for out-of-state providers and CMS used section 1135 waiver authority to waive provider screening requirements and enroll new Medicaid providers to support beneficiary access on a provisional basis. The types of provisions waived included application fees, criminal background checks, geographic licensure requirements, and site visits.

During the COVID-19 pandemic, CMS assessed states' needs through one-on-one calls with every state and key stakeholders to understand states' needs for flexibility. Using this information, CMS developed COVID-19 specific templates and checklists across a range of authorities in order to streamline submission and review process.

In a future emergency of a smaller scale or scope than the COVID-19 pandemic, CMCS may consider which flexibilities available through section 1135 waiver authority (or other authorities) are most applicable to the specific state or states involved. CMCS would then determine which flexibilities should be approved in light of its assessment of each state's unique situation.

Step 3: Assess Impact on Health Care Delivery System

The CMCS team will need to assess the impact of the emergency on the ability of the health care delivery system (Medicaid and CHIP provider networks) to provide services through meetings with states and key stakeholders such as provider groups. CMS may also want to consider various mechanisms/strategies to allow states to address payment methodologies and leverage managed care flexibilities, including modifications to managed care contracts and rates. CMCS will need to coordinate closely with other CMS Centers and Offices to support providers and the health care delivery system.

Many section 1135 and other flexibilities needed are under the purview of other agency components, including CM and CCSQ.

EXAMPLES FROM PREVIOUS EMERGENCY RESPONSES

In response to emergencies and based on states' needs, CMCS may issue waivers, expenditure authorities, and flexibilities to enable providers and health care systems to effectively deliver services during the emergency.

Hurricanes: Allow states and territories to provide out-of-state medical coverage to eligible Medicaid beneficiaries who are evacuated to a different state, rather than requiring that such beneficiaries establish residency and apply for Medicaid coverage in their new temporary location. Managed care plans will coordinate with the host state(s) to cover out-of-state medical care.

Medicaid managed care options in responding to COVID-19: Allow state Medicaid agencies to temporarily modify provider payment methodologies and capitation rates under their Medicaid managed care contracts to address the impacts of the PHE while preserving the systems of care and access for Medicaid beneficiaries. Options under managed care contracts include, for example:

- Adjust managed care capitation rates exclusively to reflect temporary increases in Medicaid fee for-service (FFS) provider payment rates where an approved state-directed payment requires plans to pay FFS rates
- Require managed care plans to make certain retainer payments allowable under existing authorities to certain habilitation, HCBS and personal care providers to maintain provider capacity and access to services
- Use state-directed payments to require managed care plans to temporarily enhance provider payment under the contract

Telehealth and other remote services: Provide guidance and technical assistance to states on Medicaid flexibility to use telehealth as a service delivery method to ensure a provider's ability to continue to offer services.

Step 4: Establish CMCS Organizational Response Structure

The CMCS leadership team, in coordination with CMS leadership, should consider how CMCS staffing and administrative processes may need to be adapted to respond to the emergency. This may include creating cross-functional teams to augment the work of CMCS Groups, making temporary shifts in work assignments, reprioritizing existing work, and modifying processes to move more quickly, such as establishing mechanisms for expedited approval of state requests. The degree to which the CMCS organizational response structure differs from normal operations will vary depending on the scope and scale of the emergency.

CMCS Organizational Response Structure Options

CMCS leadership will need to determine the features of the organizational response structure. Options include:

- Temporarily assigning staff (single or multiple staff) to coordinate CMCS efforts across Groups and act as a liaison to the OA and the Office of Emergency Preparedness Response Operations (EPRO)

- Identifying staff with appropriate subject matter expertise and assigning them specific responsibilities for components of the emergency response
- Establishing cross-functional teams to manage work that requires collaboration across Groups
- Implementing mechanisms to manage the volume of work, particularly for emergencies with broad scale and scope, including teams and processes to assess state requests and assign work to relevant Groups/Divisions
- Establishing processes for expedited clearance of policy guidance and approval of state requests related to the emergency

Table 1-3: CMCS Teams and COVID-19 Response Work

TEAM	DESCRIPTION
1135 Waiver Team	Led by the Medicaid & CHIP Operations Group (MCOG), the 1135 Waiver Team was stood up on March 16, 2020 and was tasked with handling several waves of state section 1135 waiver requests. This team, and the subset 1135 Waiver Team SWAT Team, assessed state requests, recommended approval for what could be authorized using 1135 authority and redirected state submissions that included requests that went beyond 1135 authority to the Triage Team. This team coordinated with other CMCS Groups and the Office of General Counsel (OGC) if there were questions about whether a request could be granted.
Appendix K Team	Led by the Division of Long-Term Services & Supports within the Disabled & Elderly Health Programs Group (DEHPG), the Appendix K Team worked with state Medicaid agencies to approve flexibilities related to home and community-based services. The work of the Appendix K Team built on prior use of Appendix K flexibilities from other PHEs (e.g., Hurricane Sandy).
CHIP Disaster SPA Team	Led by the Children & Adults Health Programs Group (CAHPG), the CHIP Disaster SPA Team handled CHIP SPAs related to the PHE. This team also developed tools for CHIP agencies to streamline their submissions and reviewed section 1135 and 1115(a) submissions to determine whether there were implications for CHIP, as well as identified state CHIP-related technical assistance needs.
Emergency IT Funding Team	Operated out of the Division of State Systems in the Data & Systems Group (DSG), the Emergency IT Funding Team expedited IT funding requests following existing protocols that allowed funding to become effective as of the date of the submission of the request (as opposed to the date of approval). This team helped develop FAQ responses related to emergency IT funding and held one-on-one calls with states to review their requests.
Medicaid Disaster SPA Team	Convened by the Office of the Center Director (OCD), this cross-cutting team included individuals from CAHPG, MCOG, the Financial Management Group (FMG), DEHPG, and the Operations Services Group (OSG) to conduct expedited intake, review, and processing of Medicaid Disaster SPAs.

TEAM	DESCRIPTION
Triage Team	The Triage Team started in late March and included representatives from CAHPG, DEHPG, the State Demonstrations Group (SDG), MCOG, FMG and DSG to review comprehensive requests from states and determine the correct authority. The Triage Team completed an assessment of a state's request (often building on the work of the 1135 Waiver Team), and then a team member provided that state with written feedback on the appropriate authorities needed to execute its requests. The Triage Team reviewed hundreds of state requests in a very short amount of time.

Step 5: Establish Communication Strategies

It is important that CMCS establish communication strategies to ensure clear and timely information is shared with key groups. These groups include state Medicaid and CHIP agencies, CMS leadership, CMCS staff and certain stakeholder organizations. State Medicaid and CHIP agencies need to receive timely information from CMCS about what flexibilities and options are available to them in responding to an emergency. At the same time, CMS leadership needs to hear from CMCS leaders about the impact of an emergency on the ability of states to run their Medicaid and CHIP programs.

CMCS can use a range of methods in its communication strategies, for example:

- Posting information on the Medicaid.gov website including creation of a new webpage focused specifically on the emergency
- Use of social media, press alerts and press releases
- Use of distribution lists through the GovDelivery platform
- One-on-one TA calls with state Medicaid and CHIP agency staff
- Targeted TA to state Medicaid and CHIP agencies with CMCS teams
- All-state calls
- External stakeholder calls

Communication, internally and with states, needs to start early even if a full communications strategy has not been developed and finalized. Close coordination with the CMS Office of Communications is necessary for public-facing releases and the use of social media, consistent with regular operations. The degree to which the CMCS's communication strategy differs from normal operations will vary depending on the nature of the emergency.

- **State Medicaid and CHIP agencies**
  CMCS is the liaison between CMS/HHS and state Medicaid and CHIP agencies that are affected by a disaster or PHE. As such, CMCS should reach out to states in advance of an emergency, to the extent feasible, and after an emergency. Initial communications are intended to convey to states that CMCS will support them during the crisis, including approving state requests for flexibility, to the extent allowable. During these initial communications, CMCS should ask states how the emergency has impacted their operations as described in Step 2, "Assess state Medicaid and CHIP agency operations and needed flexibilities". After these initial communications, CMCS can continue engaging states in ongoing communications and share resources and information that are helpful to states. Multiple methods of communication can

be used as part of the communication strategy such as one-on-one calls, All-State calls, posting on Medicaid.gov and distributions using listservs. The frequency and breadth of communications methods with states will depend on the number of states impacted and potential length of the emergency.

- **CMS leadership**
  CMCS is the primary conduit by which CMS leadership learns of the impact of an emergency on state Medicaid and CHIP agencies' ability to operate. As a result, it is critical that CMCS leadership share timely and regular updates with CMS leadership through existing and / or newly created communication channels, such as standing calls or meetings. New policy will also need to be cleared through CMS leadership as appropriate.
- **CMCS staff**
  Based on the scope of the emergency, it is important that CMCS staff hear from leadership in an employer capacity and if there are temporary organizational changes. Because CMCS follows the agency's lead on employee communications, the content of information is typically determined by the Office of the Chief Operating Officer within OA and the Office of Human Capital (OHC). CMCS leadership may consider sharing the content of agency communications, although CMCS may need to ensure clarity with these communications and offer additional detail. To the extent that staff are engaged in a disaster or PHE response, it will be critical to communicate information and roles and responsibilities to CMCS staff.
- **Key stakeholder groups**
  Communicating with key stakeholder groups will vary depending on the type, size, scope, and population affected by the emergency. Key stakeholders can include those representing state Medicaid, CHIP and HCBS agencies, provider groups, health plan associations and consumer or beneficiary advocates. CMCS may engage a broad group of associations and advocacy groups by holding regular meetings and sharing guidance related to the emergency. Alternatively, CMCS could reach out to a limited number of stakeholder groups to gather and share targeted information. Working with stakeholders through conference calls and individual TA may help CMCS assess the needs of beneficiaries, providers and health plans and identify issues that CMCS staff may not hear otherwise. This, in turn, informs the development of policy and resources, such as templates and checklists that can assist state Medicaid and CHIP agencies in responding quickly to an emergency.

Step 6: Establish a Technical Assistance Strategy to Support State Medicaid and CHIP Agencies as They Respond to a Public Health Emergency

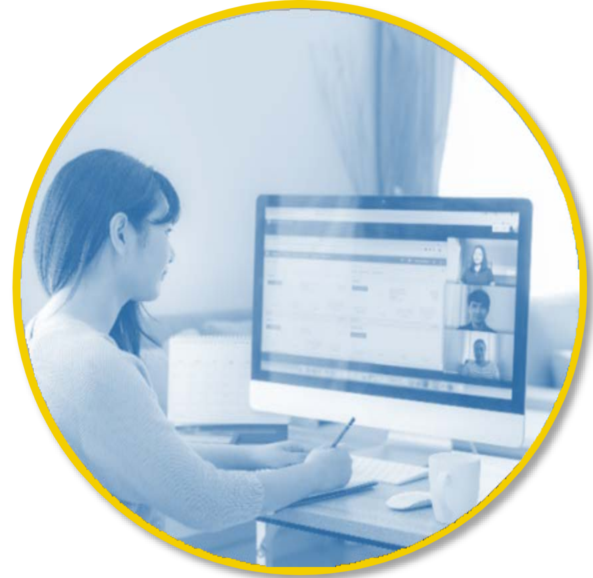
As the CMCS team develops its response, establishing a TA strategy and providing TA to state Medicaid and CHIP agencies is critical. CMCS is the primary entity representing state Medicaid and CHIP agency perspectives within CMS and the Department, and CMCS needs to be the conduit by which state Medicaid and CHIP agencies receive TA and information about an emergency. The degree to which CMCS needs to develop a TA strategy depends on the scale and scope of the emergency. For instance, wildfires and hurricanes may require a more targeted strategy, whereas a pandemic could affect program implementation and policy development nationwide.

CMCS Technical Assistance Options for States

CMCS needs to not only manage incoming requests from state Medicaid and CHIP agencies but also proactively provide TA options to them. The TA options that CMCS makes available to state Medicaid and CHIP agencies will need to be deployed rapidly as they move quickly to implement their own response to an emergency.

TA options include:

- **Written guidance**, for example:
  - **CMCS Informational Bulletins:** These information bulletins share information, address operational and technical issues, and highlight initiatives or related efforts. They generally do not establish new policy or issue new guidance.
  - **FAQs:** These can clarify and provide guidance on regulatory or subregulatory issues. They can also be used to address operational and technical issues. In addition to point-in-time releases, CMS offers an interactive FAQ library. See **Table 1-5** for the categories of COVID-19 FAQs.
  - **State Health Official letters:** These further clarify and communicate agency policies. They also provide guidance and clarify statutory and regulatory issues and generally apply to both Medicaid and CHIP programs.
  - **State Medicaid Director letters:** These further clarify and communicate agency policies. They also provide guidance and clarify statutory and regulatory issues but are Medicaid-specific.
- **One-on-one TA:** State Medicaid and CHIP agencies need various levels of engagement, including in-depth, one-on-one TA. Individual calls can be held with states to address a wide range of needs that are specific to a given state, such as quickly identifying the appropriate authority needed to access a particular flexibility or providing assistance with the submission process and review process related to multiple authorities. These calls typically involve the CMCS state lead and subject matter experts on relevant topics.
- **All-state calls:** All-state calls are a convening vehicle even outside of an emergency. Leveraging this familiar format can help CMCS share information quickly with state Medicaid and CHIP agencies and understand their questions.
- **TAGs:** CMCS maintains TAGs to engage with state Medicaid and CHIP agencies and stakeholders in select topic areas. Through TAGs, CMCS communicates with state staff on policy development and implementation and can do a deeper dive on subject areas that may not be appropriate for an All-State call format. The work involved in a response to an emergency can come through many CMCS teams, and it is important that there be a coordinated effort to filter the response information through these TAGs as applicable. TAGs can also be used to gather state



feedback and to share information with targeted state audiences. See **Table 1-4** for a list of CMCS TAGs.

Table 1-4: CMCS TAGs

NAME OF TAG	CMCS GROUP
Children's Coverage TAG and Regional Representatives Call	CAHPG
CMS Coordination of Benefits/Third Party Liability TAG	DEHPG
Eligibility TAG	CAHPG
Managed Care TAG	DEHPG
Medicaid Enterprise Systems TAG	DSG
Oral Health TAG	CAHPG
Quality TAG	CAHPG
Tribal Affairs Tribal TAG	CAHPG
1115(a) Monitoring and Evaluation State Representative TAG	SDG

EXAMPLES FROM PREVIOUS EMERGENCY RESPONSES

During the COVID-19 pandemic, to address the wide range of questions and concerns states had, CMCS developed FAQs that were a major vehicle for issuing guidance to states. Through August 2020, CMCS issued five batches of general FAQs and two batches of FAQs specific to COVID-19-related legislation. The FAQs were posted on Medicaid.gov and distributed on the Medicaid.gov email lists.

In a future emergency of a smaller scale or scope than the COVID-19 pandemic, CMCS may consider using the topics addressed covered in **Table 1-5** as a starting place to structure to development of FAQs. Specific FAQs that would apply to an emergency could then be developed under these topics. CMCS may also find in this circumstance that some topics are not relevant, depending on the nature of the emergency.

Table 1-5: COVID-19 Frequently Asked Questions Topics

I.	EMERGENCY PREPAREDNESS AND RESPONSE
II.	**ELIGIBILITY AND ENROLLMENT**

a. Application and Renewal Processing
b. Premiums and Cost-Sharing
c. Eligibility
d. Notice and Fair Hearings
e. Presumptive Eligibility
f. Verification
g. Basic Health Program
h. Coverage for American Indians and Alaska Natives
i. Continuing Coverage Under section 6008 of the Families First Coronavirus Response Act
j. Optional COVID-19 Testing Group
k. Miscellaneous

III. BENEFITS	
a. COVID-19 Testing b. Telehealth c. Home and Community-Based Services d. Pharmacy/Prescription Drugs e. Money Follows the Person Program	f. Non-Emergency Medical Transportation g. Health Resources and Services Administration Uninsured Provider Fund/Medicaid Coordination of Benefits h. Miscellaneous
IV. FINANCING	
a. Administrative Claiming b. Advance and Retainer Payments c. Federally Qualified Health Center and Rural Health Center Services	d. Payment Rates and Methodologies e. Upper Payment Limits f. Miscellaneous
V. MANAGED CARE	
a. Contracts and Rates b. Quality Measurement	c. Miscellaneous
VI. INFORMATION TECHNOLOGY	
a. Funding b. Health Information Exchange c. Transformed Medicaid Statistical Information System	d. Telework e. Miscellaneous
VII. MISCELLANEOUS	
a. Quality Reporting b. Workforce Issues	c. Section 1115(a) Demonstrations d. Other

Step 7: Establish Mechanisms for Tracking and Monitoring

CMCS will need to establish a mechanism for tracking, monitoring, and reporting during an emergency. A CMCS team should determine whether there is a process in place for monitoring emerging issues and how CMCS is responding. This may be led by EPRO, at the request of OA, and CMCS may need to contribute to this agency-wide effort. Alternatively, the CMCS Center Director may want his/her own method for tracking and monitoring. Depending on the need and who is requesting it, a team can review existing tools designed to capture real-time feedback and adjust the plan as needs evolve. The most important scale and scope factor to consider for this step in CMCS's response is the impact of the emergency on CMCS staff and state operations. As CMCS develops its methods for monitoring, it could consider whether it reviews flexibilities adopted by states during the emergency and assesses their impact on outcomes. This is especially important when there are precedent-setting approvals and / or a large volume of approvals. Tracking, monitoring, and reporting are aspects of the response that cannot happen without smoothly running operations at the federal and state levels. CMCS should consider how to ease the burden of reporting on state Medicaid and CHIP agencies and its own staff.

EXAMPLES FROM PREVIOUS EMERGENCY RESPONSES

During the COVID-19 pandemic, CMCS used a SharePoint tool, called the Master Tracker, to log and track state and stakeholder questions and formal submissions received from states. Prior to the PHE, tracking was done primarily at the Group level, and each CMCS Group used its own processes and tools to manage inquiries from state Medicaid and CHIP agencies and submissions that required review and approval. The Master Tracker centralized workflow and reporting to one central SharePoint site supported by a CMCS Data & Systems Group contractor.

From a workflow perspective, CMCS State Leads, Analysts, and Project Officers were responsible for entering state questions or formal submissions into the tool and facilitating communications and reviews. CMCS Groups were responsible for creating the response to questions and resolving official submission requests in the tracker.

For reporting, Group and Office of the Center Director leadership monitored the status of requests and inquiries by different authorities. **Figure 1-1** summarizes the COVID-19 response actions that CMCS had received and decided on as of November 15, 2020.

Figure 1-1: COVID-19 Response Actions as of November 15, 2020

Action	Received	Decision
1135 Waivers*	131	133
Medicaid Disaster SPA	166	143
CHIP Disaster SPA	49	46
1115(a) Demonstrations	48	35
1915(c) Appendix K	168	157
IT Funding Request	46	45
Regulatory Authority Concurrence	52	52
Grand Totals	660	611

**Due to the approval processes for 1135 waivers which allow multiple approval letters for a single submission, there are more decisions than submissions received to date.*

Step 8: Deploy Strategies Needed to Support CMCS Operations and Staff Affected by the Emergency

Using information from the assessment of impact on CMCS operations and staff outlined above, the team may need to support staff and operations affected by the emergency. If affected, then the team would work with OA, including the Chief Operating Officer, OHC, and others in following the CMS

Pandemic Plan and/or Continuity of Operations Plan so that essential operations continue. If staff are working remotely, then coordination would occur with the Office of Information Technology for ensuring that the CMCS workforce has hardware (e.g., laptops, cell phones, portable devices to access Wi-Fi) and training, if necessary.

EXAMPLES FROM PREVIOUS EMERGENCY RESPONSES

Workforce policy changes and flexibilities have been implemented in various scenarios:

- CMCS expanded the use of technology platforms and tools to better enable tele/video conferencing, document sharing, collaboration, and engagement.
- CMCS established weekly Center-wide all-staff meetings to communicate messages regarding guidance coming from OA and OHC on topics including workplace flexibilities and administrative leave.
- In collaboration with OHC and the Employee Assistance Program, CMCS offered sessions on how to effectively work remotely and deal with stress and anxiety associated with the PHE and changing work environment.
- The Office of Program Operations & Local Engagement worked with OHC and its geographical Federal Executive Board to issue guidance about office closures invoking liberal leave or work- from-home flexibilities for state/regional emergences. During Hurricane Katrina, CMCS staff in Louisiana, Mississippi, Alabama, and Florida experienced office closures and either worked from home or, in situations where it was difficult to work, had to use administrative leave.

The infectious risk associated with COVID-19 required a transition to maximum telework. In preparation, CMCS collaborated with OIT to test system connectivity through virtual private networks, capacity for video conferencing and teleconferencing, and employees’ ability to adjust to working remotely.

ANNEX L – Revision History

RECORD OF CHANGES

Rev.#	Effective Date	Author	Description of Change	Justification for Changes
n/a	09/2011	OPE/EPRO	Revised organizational structure, roles and responsibilities, incorporated Telework Policy.	PPD-8 updates dated March 30, 2011
1.0	09/2019	OA/EPRO		Template provided by HHS/ASPR
2.0	10/2019	OA/EPRO	Comports with HHS/ASPR template, specific to CMS.	
2.1			Non-published draft	
2.2	02/2020	EPRO	Updates to Pandemic Plan to be more specific to CMS.	Made the generic template reflect CMS work.
2.3	02/2020	EPRO	Updates to Pandemic Plan to include Component input.	Gain input from the components to ensure actions, triggers, and timelines are captured.
2.4	03/2020	EPRO	Additional component input added, as well as alignment to new HHS & CDC guidance.	Complete component capture and to adjust to new guidance to ensure sync with HHS planning efforts.
3.0	07/2020	OA/EPRO	Extensive update consisting of: Revised structure to align with FEMA-recommended guidelines for emergency plans, created several new sections (Section 4 - 8) covering Policy response, Stakeholder engagement, Operational response, Pandemic governance and Information sharing & scenario planning, added multiple Annexes detailing COVID-19 policy actions, templates, and stakeholder engagement example output, and updated pandemic plan throughout with learnings from the COVID-19 response and CMS' employee feedback .	Ensure best practices from the agency's (then ongoing) COVID-19 response are incorporated into the pandemic plan.

Rev.#	Effective Date	Author	Description of Change	Justification for Changes
3.1	10/2020	OA/EPRO	Removed Annexes C-J and other edits for public release. These annexes contained paper versions of publically available information and/or internal planning aides to be used to operationalize the plan.	Ensure agency base plan transparency for stakeholders.

ANNEX M – Approvals

Signature: X ______________________________

Date: MM/DD/YYYY

Print Name: Type your name here.

Title: Type your title here.

Role: Type your role here.