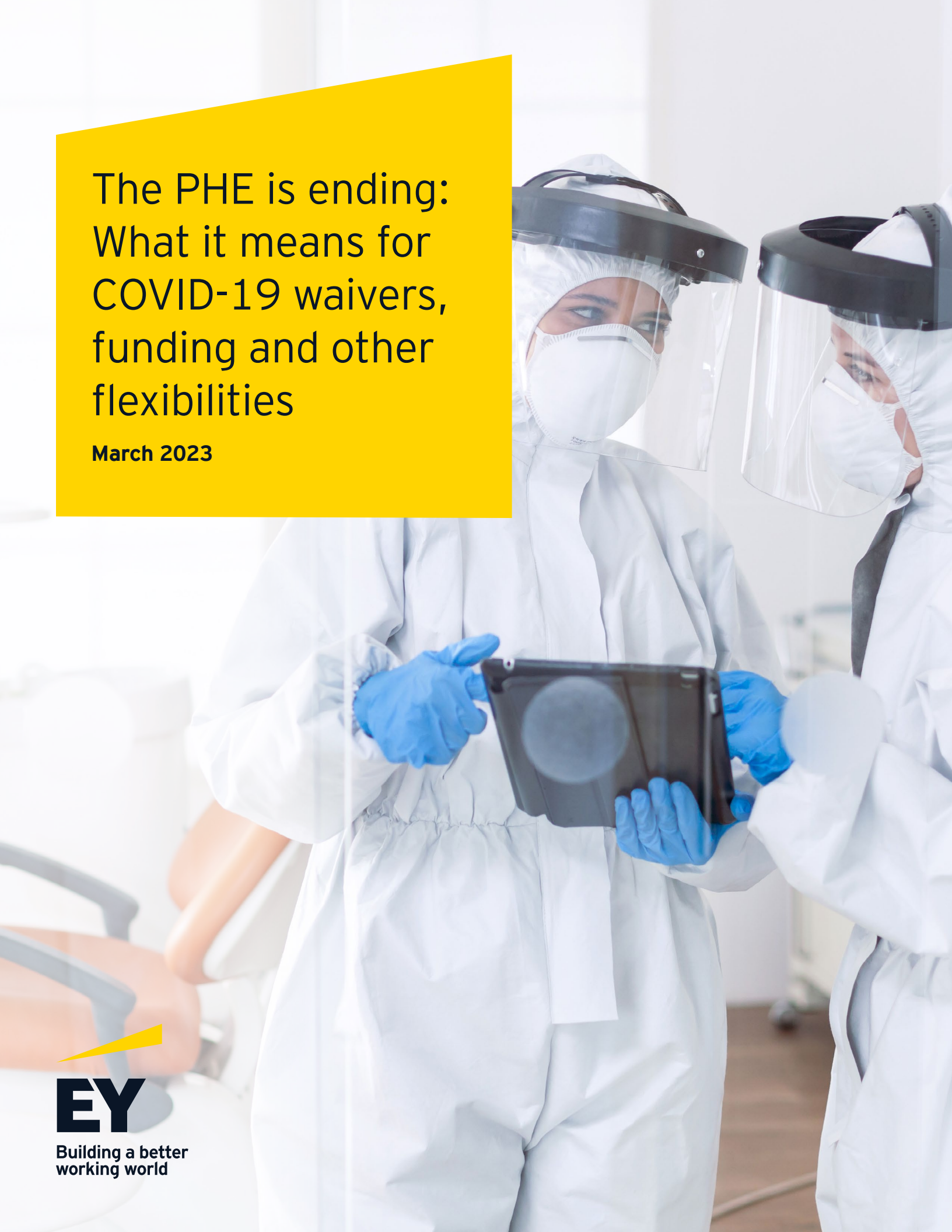
The PHE is ending: What it means for COVID-19 waivers, funding and other flexibilities

March 2023



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Abstract

Throughout the COVID-19 pandemic, the Department of Health and Human Services and related agencies have waived or modified hundreds of health regulations, many of which were tied to the public health emergency, which is now set to expire on May 11, 2023. Washington Council Ernst & Young (WCEY) has combed through the regulations and statutes to provide an in-depth overview of the status of existing COVID-19 waivers, emergency funding and other flexibilities — and the regulatory or congressional actions needed to extend or make permanent those flexibilities.

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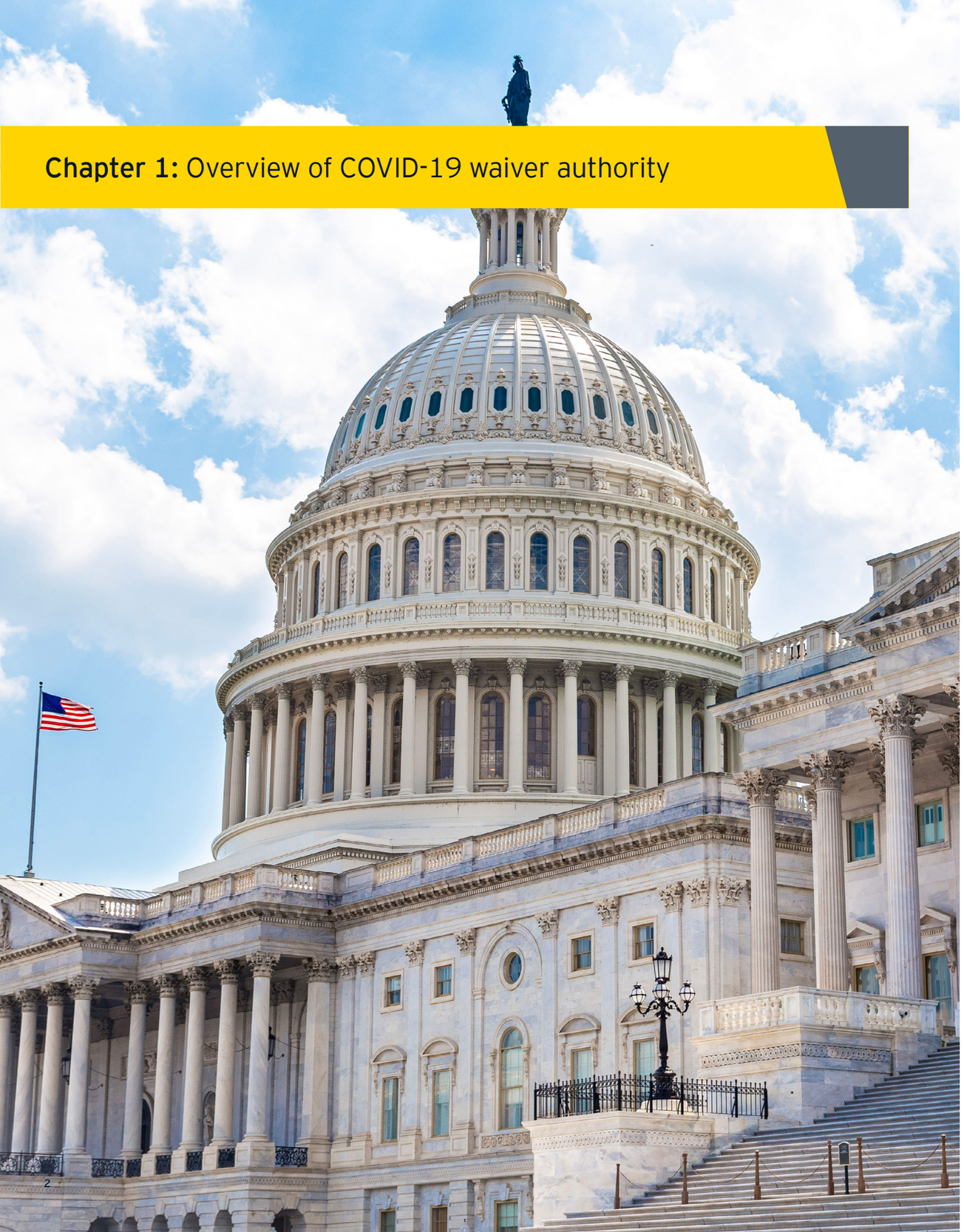
Introduction

After more than two years, the public health emergency (PHE) for the COVID-19 pandemic is set to end on May 11, 2023. The expiration of the PHE has wide-ranging implications for health care industry leaders whose companies have operated in a more relaxed regulatory climate and benefited from an influx of government dollars intended to facilitate and support testing, vaccination and care delivery throughout the pandemic.

While many of the health care flexibilities issued during the pandemic are set to expire at the end of the PHE, policymakers at the federal and state level took advance action to extend, make permanent or roll back certain COVID-19 waivers. For example, the Centers for Medicare & Medicaid Services (CMS) began issuing fact sheets and updating guidance on how it is evaluating PHE-related flexibilities months ago.[1] This briefing provides an in-depth overview of the status of existing COVID-19 waivers and their potential paths forward. Industry leaders should act now to verify that they are in compliance and have a game plan for a smooth transition for patients and staff when waivers lapse and certain pre-pandemic regulatory realities resume.

This overview will not cover all of the health care flexibilities granted during the PHE; the Department of Health and Human Services (HHS) alone has waived or modified nearly 200 federal health regulations, and CMS has processed more than 250,000 1135 waiver requests throughout the COVID-19 pandemic. In addition, each state has taken a unique policy approach to its emergency response. Instead, this overview focuses on the federal waivers, flexibilities and funding streams that are top of mind for providers, payers and other industry leaders.



Chapter 1: Overview of COVID-19 waiver authority

The federal government has broad authority to issue emergency declarations that provide federal agencies with the flexibility to respond to PHEs.

In response to the pandemic, the federal government invoked statutory authority to declare emergencies enabling agencies and states to waive or modify requirements for federal health care and workforce requirements. In addition, Congress throughout the pandemic has passed legislation that broadened HHS's authority to waive certain regulations in the wake of a PHE and has amended statutes to directly provide or extend flexibilities related to the pandemic. Below is an overview of the major emergency declarations and legislation that provided the COVID-19 waiver authority.

Emergency declarations

1

A **public health emergency** was issued by the HHS secretary on January 31, 2020, under the Public Health Service Act (PHSA). The declaration gives the HHS secretary the authority to waive or modify certain federal requirements, access funds in the Public Health Emergency Fund, and make temporary personnel changes.[2,3] The PHE is set to expire on May 11, 2023.[4]

2

An **emergency declaration** was issued by the HHS secretary under the Federal Food, Drug, and Cosmetic (FD&C) Act in February 2020.[6] This declaration provides the Food and Drug Administration (FDA) the authority to issue emergency use authorizations and remains in effect until the HHS secretary retracts it.[7]

3

National emergency declarations were issued by President Donald Trump in March 2020 under the National Emergencies Act (NEA) and the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act). Declarations made under the NEA automatically expire after one year unless ended or renewed by the president or ended by Congress. President Joe Biden in February 2022 extended the current emergency and on January 30 announced plans to end the declaration on May 11.[4,5] The Stafford Act enables a president to declare an "emergency" or "national disaster" to provide federal support to individual states or tribes. The combined declaration of both a PHE by the HHS secretary and either an emergency or disaster by the president under either the NEA or the Stafford Act gives the HHS secretary authority to temporarily waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act requirements during a PHE.[6]

4

An **emergency declaration** was issued by the HHS secretary under the Public Readiness and Emergency Preparedness (PREP) Act in March 2020.[8,9] This declaration provides liability immunity for actions related to the COVID-19 pandemic. The HHS secretary can amend the declaration as justified but must set an end date, which is currently October 1, 2024.

Federal legislation

1

Coronavirus Preparedness and Response Supplemental Appropriations Act. This act was signed into law on March 6, 2020. The bill provided $8.3 billion in emergency funding to help federal agencies respond to COVID-19 in the United States and abroad, supporting vaccine development and public health funding. The act also authorized HHS to waive certain traditional Medicare telehealth requirements during the national emergency.

2

Families First Coronavirus Response Act (FFCRA). This act, signed into law on March 18, 2020, provided $104 billion to support COVID-19 response efforts and required private health plans and Medicare to cover COVID-19 testing at no out-of-pocket cost to the patient.

3

Coronavirus Aid, Relief, and Economic Security (CARES) Act. The $2.2 trillion act, which was signed into law on March 27, 2020, included provisions to support Americans, small businesses and the health care industry. The act established the Provider Relief Fund and broadened the HHS secretary's authority under Section 1135 of the Social Security Act (SSA) and Section 319 of the PHSA, enabling CMS in May 2021 to issue additional 1135 waivers and to waive statutory Medicare telehealth requirements during any PHE.

4

Paycheck Protection Program and Health Care Enhancement Act. The act, which was signed into law on April 24, 2020, provided $484 billion to replenish the Paycheck Protection Program and support public health response.

5

American Rescue Plan Act of 2021. This act was signed into law on March 11, 2021. The $1.9 trillion stimulus bill provided additional financial relief to individuals, families and businesses and included several provisions to support public health response and COVID-19 vaccination efforts.

6

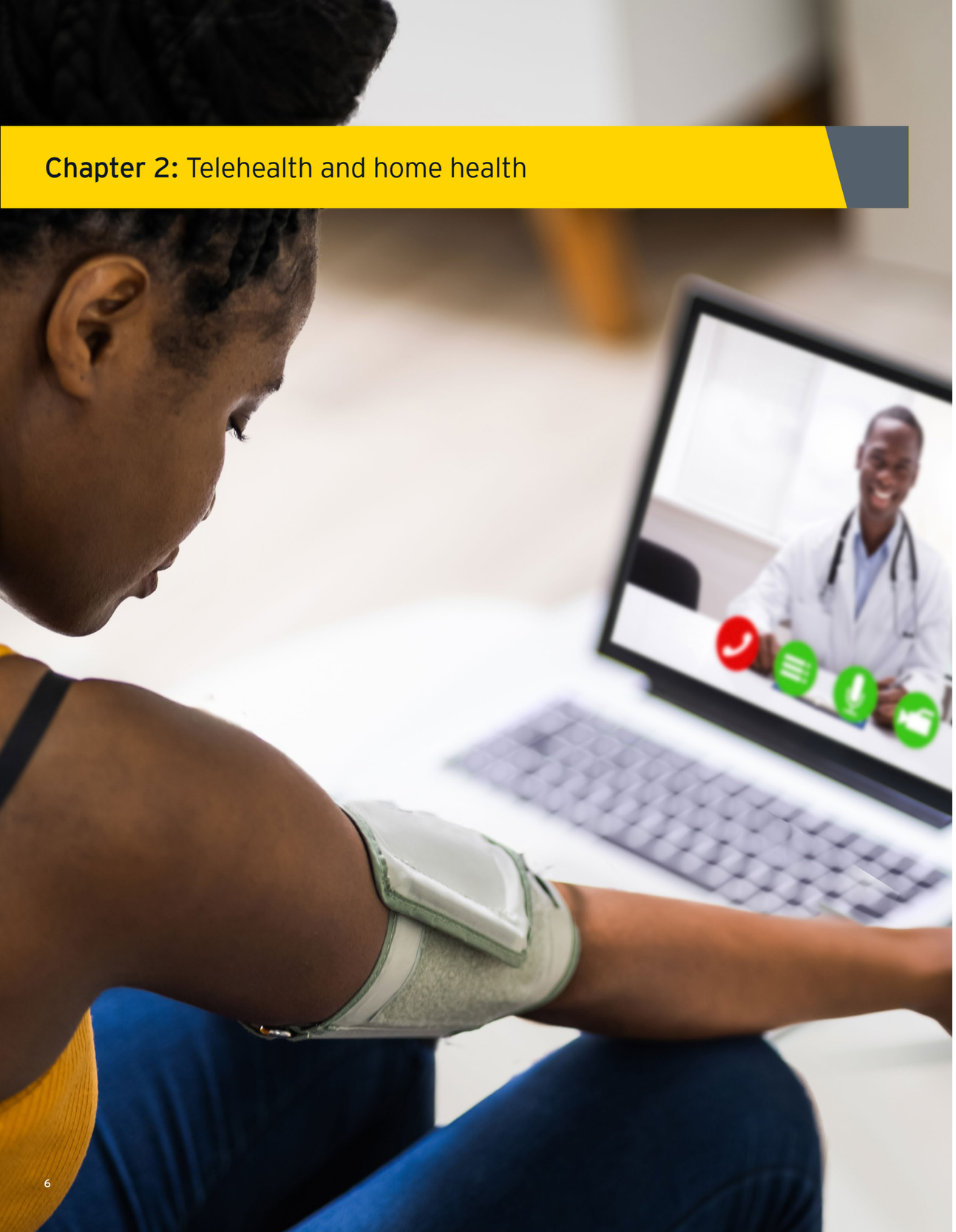
Consolidated Appropriations Act, 2022 (CAA 2022): The $1.5 trillion omnibus bill, which was signed into law on March 15, 2022, funded the government through the remainder of fiscal year (FY) 2022. CAA 2022 included several provisions to extend certain telehealth waivers beyond the PHE and called for studies into telehealth use to inform longer-term policymaking.

7

Inflation Reduction Act (IRA): Signed into law on August 16, 2022, the IRA included provisions to improve access to vaccines for Medicare beneficiaries and adults enrolled in Medicaid and CHIP, as well as to temporarily extend enhanced Affordable Care Act (ACA) subsidies for marketplace enrollees through 2025.

8

Consolidated Appropriations Act, 2023 (CAA 2023): The $1.5 trillion omnibus bill, which was signed into law on December 29, 2022, funded the government through the remainder of FY 2023. The bill included several provisions to extend flexibilities granted during the PHE, including extending certain telehealth waivers, the Acute Hospital Care at Home waiver program and a provision allowing high-deductible health plans to offer telehealth before the deductible through CY 2024. The bill also sunsets the Medicaid continuous coverage requirement effective April 1, extends Medicare Part D coverage for oral antiviral drugs granted emergency use authorizations (EUAs) and more.



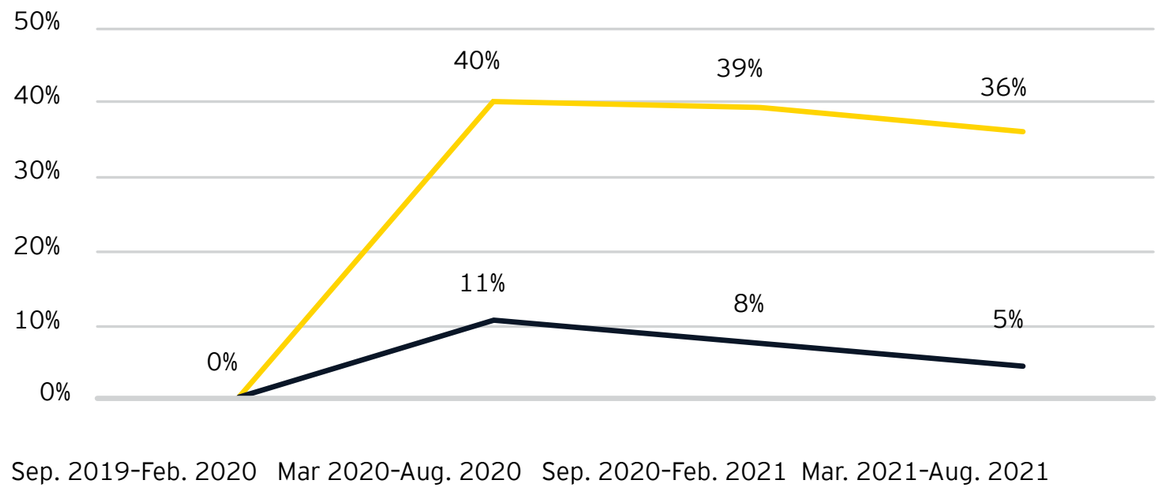
Chapter 2: Telehealth and home health

Telehealth providers, suppliers and vendors must act now to understand and comply with the patchwork of state and federal telehealth regulations that will exist when the PHE ends.

Regulatory authority over telehealth varies by the type of plan: The federal government directly oversees Medicare and self-insured plans, while Medicaid and fully insured health plans are subject to both federal and state requirements. Throughout the PHE, the Trump and Biden administrations, Congress, states and private payers took steps to increase access to telehealth and home health services to ease the burden on hospitals and providers overrun with COVID-19 patients and to protect patients and providers from unnecessary exposure from in-person visits.

As a result, telehealth use in 2020 soared among both privately and publicly insured patients, particularly for mental health and substance use disorders. And while telehealth utilization rates have declined since the early days of the pandemic, they remain well above pre-pandemic levels and are now an expected care option among patients.

Share of outpatient visits delivered by telehealth, 2019–21



Source: Kaiser Family Foundation, "Telehealth Continues to Account for More Than a Third of Outpatient Visits for Mental Health and Substance Use Services Well into the COVID-19 Pandemic," 15 March, 2022

For the past year, states have been rolling back their emergency declarations and health care-related flexibilities. There is now a national conversation occurring in both the federal and state legislatures around which COVID-19 flexibilities should remain in place long term, with many of those conversations centered on telehealth. In many cases, providers' and payers' ability to continue offering telehealth services will depend on the future regulatory, legislative and payment landscape at both the state and federal level.

Telehealth waiver trends at the federal level

At the federal level, continued telehealth use requires both regulatory and legislative changes, and the Biden administration and lawmakers have been actively engaged in these discussions.

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Covered telehealth services Category 3 services: CMS created a temporary status to add services to the telehealth list that do not fit into Categories 1 or 2.			■			CMS has the regulatory authority to add certain telehealth services to the Medicare telehealth list which are payable under the MPFS if they meet CMS criteria for inclusion. CMS has used the MPFS rulemaking process to propose and add new services. The CY 2023 MPFS rule extends Category 3 services through the end of CY 2023 and extends other interim services 151 days post-PHE. CMS did note these dates could change. For example, CMS said if the PHE remains in place through most of CY 2023, it could extend the expiration date for Category 3 services to 151 days post-PHE.
Non-category 3 interim services: During the PHE, CMS reimbursed for some telehealth services but did not give those services Category 3 status.		■				
Tele-mental health: CMS waived requirements for in-person visits within six months of the original assessment and every 12 months after. Source: CY 2023 Medicare Physician Fee Schedule (MPFS) final rule				■		Congress in the omnibus package delayed the in-person requirement for tele-mental health services through CY 2024.

Congress has already acted to temporarily extend certain federal telehealth waivers and is currently considering which telehealth flexibilities to extend further. In addition, CMS is conducting a regulatory review to identify areas where it has the legal authority and the supporting evidence to extend or make permanent certain telehealth flexibilities.

The key concerns policymakers are working to address are overall costs and offsets, health equity, payment parity, modality and geographic location restrictions, quality of care, audio-only care, and the impact on fraud, waste and abuse. For example, the Congressional Budget Office (CBO) estimated that extending certain telehealth policies just five months would cost $633 million.[10] The Committee for a Responsible Federal Budget extrapolated that figure forward, predicting a cost of $25 billion for 10 years.[11]

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Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Geographic and originating site CMS waived geographic restrictions that limited telehealth to certain rural areas and expanded the list of "originating sites," or the physical location of the patient, to include any site in the US, including the patient's home. Source: CMS FAQs				Physical health	Mental health	Congress extended this flexibility through CY 2024 and permanently removed geographic restrictions for mental health services, allowing the patient's home to be an originating site with certain in-person requirements. CMS codified the mental health change in the CY 2022 MPFS rule. The CY 2023 MPFS rule delayed the in-person requirements for mental health until 151 days after the PHE ends. Additional congressional action would be required to modify the legal definition of an "originating site."
Originating site facility fee CMS paid the originating site fee to the hospital if the patient's home or temporary expansion site is a provider-based department of the hospital and the patient is registered as an outpatient. For CY 2023, the rate is $28.64. Source: Interim final rule, CAA 2022	■					Congress in the CAA 2023 restricts the facility fee payment to pre-PHE originating sites (which does not include a patient's home) beginning at the end of the PHE through December 31, 2024. Additional congressional action would be required to permanently or temporarily modify the current statute and allow facility fees to be paid when the originating site is the patient's home.

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Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Distance site providers and facilities CMS expanded types of providers and facilities eligible to bill Medicare for telehealth services to all Medicare-eligible providers, adding physical therapists, occupational therapists, speech language pathologists and audiologists.						Congress in the CAA 2023 extended these flexibilities through CY 2024, and CMS in the CY 2022 MPFS rule permanently added RHCs and FQHCs to the list of distance site facilities for mental health services. Additional congressional action would be required to modify the list of eligible providers who can be reimbursed for telehealth services under Medicare as well as the list of eligible distant site providers. Geographic and state-based restrictions would still apply.
CMS expanded types of distant site facilities, or the provider furnishing telehealth services, to include rural health centers (RHCs) and federally qualified health centers (FQHCs). Sources: COVID-19 blanket waivers, CARES Act				Physical health	Mental health	
Telehealth payment rate Medicare reimbursed at the same rate (facility or non-facility) it would pay if services were provided in person for video and certain audio-only evaluation and management (E/M) visit services. Source: CMS interim final rule						Some legal experts argue CMS has the regulatory authority to change its interpretation of the existing statute. Congressional action could help clarify language on payment parity, which states that distant site providers should be reimbursed "an amount equal to the amount that such [provider] would have been paid ... had such service been furnished without the use of a telecommunications system."

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Telehealth modes (smartphone and audio only) Audiovisual telephones: CMS allowed telehealth services to be furnished via telephone if they have real-time audio-visual capabilities (i.e., smartphones). The HHS Office for Civil Rights (OCR) also is exercising enforcement discretion for popular audio-visual applications, such as FaceTime and Zoom.						CMS has the regulatory authority to revise the definition of "interactive telecommunications" to include smartphones. However, congressional action would be needed to allow audio-only devices for certain E/M services.
Audio-only telephones: CMS reimbursed for certain audio-only E/M telephone and behavioral health services, including opioid treatment programs. Sources: CMS interim final rule, OCR enforcement discretion notice, COVID-19 blanket waivers				Physical health	Mental health	Congress in the CAA 2023 extended CMS's waiver for certain audio-only services through CY 2024. In the CY 2022 MPFS rule, CMS said it will permanently pay for mental and behavioral health services furnished via telehealth, including audio-only services in certain circumstances. The HHS OCR in June 2022 issued guidance on how providers can comply with the Health Insurance Portability and Accountability Act (HIPAA) post-PHE using audio-only technology.
Provider-patient relationship Medicare providers can see both established and new patients via telehealth during the PHE, as HHS determined it would not conduct audits to verify that a prior relationship existed. Source: CMS interim final rule						CMS has the regulatory authority to remove language from code descriptions stating services be provided to an "established patient."

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Licensure/practicing across state lines Medicare and Medicaid state licensure requirements are waived when certain conditions are met. *Note: Providers are still required to adhere to state licensure requirements*. Source: 1135 waiver						Congressional action would be required to modify the SSA, which requires compliance with state licensure requirements. *Note: Federal officials have noted any changes would need to be balanced with state licensing boards' current authority.*
Direct supervision CMS allowed physician direct supervision of auxiliary personnel to be provided using real-time audio and video technology instead of in person. Source: CMS interim final rule						CMS has the regulatory authority to make this flexibility permanent. In the 2021 MPFS final rule, the CMS extended the policy through the end of the year in which PHE ends.
Teaching physician supervision The CMS allowed the direct supervision requirement to be met using real-time audio and video technology. Source: CMS interim final rule						CMS has the regulatory authority to permanently change direct supervision requirements.
Beneficiary cost-sharing Providers will not face penalties from the HHS Office of Inspector General (OIG) for waiving or reducing cost-sharing obligations for telehealth services provided to federal health program enrollees. In addition, the CMS gave Medicare Advantage (MA) plans permission to waive or reduce cost-sharing for beneficiaries impacted by the pandemic. Source: HHS OIG bulletin						The HHS OIG can reconsider, modify or terminate the policy statement at any time. Congressional action would be required to verify that providers who waive or reduce cost sharing do not run afoul of the federal anti-kickback statute.

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Diagnostic testing review CMS relaxed enforcement of the established patient requirement and expanded the list of providers that may use codes for remote diagnostic testing review. Source: CMS interim final rule						CMS has the regulatory authority to make the remote diagnostic testing review more broadly available.
Remote patient monitoring CMS relaxed enforcement of the established patient requirement and expanded the types of patients to include those with acute and chronic conditions and patients with one disease.						CMS has the regulatory authority to expand the use of remote patient monitoring codes for new patients through the regulatory process.
CMS eased telehealth restrictions on home health remote patient monitoring and adjusted regulations to temporarily allow telecommunication systems. Source: CMS interim final rule						In the CY 2021 home health rule, CMS permanently allowed home health agencies to use telecommunications technology, including remote patient monitoring and audio only, if it is reflected in the patient's care plan.
Hospice care CMS allowed a telehealth visit to serve as a face-to-face encounter needed to recertify a person's eligibility for hospice care. Source: CAA 2023						Congress in the CAA 2023 extended this flexibility through CY 2024. Additional congressional action would be needed to amend the Social Security Act and make this change permanent.
Home dialysis Telehealth was able to serve as the face-to-face evaluation for both the patient evaluation and clinical examination of the vascular site. Source: COVID-19 blanket waivers						Congressional action would be required to make these changes permanent. Regulatory action may suffice to make the clinical examination of the vascular site permanent.

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Nursing homes CMS waived the requirement for physician and non-physician practitioners to visit nursing home residents in person, allowing the use of telehealth when appropriate **(terminated).** Source: COVID-19 blanket waivers	■	■	■	■	■	In April 2022, CMS issued a memo updating COVID-19 emergency declaration blanket waivers that ended this and other flexibilities 30 days from publication. This telehealth-related waiver is no longer in effect. Source: Updated COVID-19 Blanket Waivers
Acute Hospital Care at Home (AHCH) waiver CMS allowed individual hospitals to apply to waive certain Conditions of Participation in Medicare to provide hospital-level care to Medicare patients at home. Source: CMS.gov				■		Congress in the CAA 2023 extended the waiver program until December 31, 2024.
Hospital Without Walls Initiative CMS allowed hospitals to treat patients in alternative care settings outside of the hospital, provided the space is approved by the state. Source: CMS fact sheet	■					Congressional action would be required to extend or make permanent flexibilities enabling the Hospital Without Walls Initiative

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	**End of PHE (May 11)**	**151 days post-PHE**	**End of CY 2023**	**End of CY 2024**	**Permanent policy**	
Prescribing controlled substances The Drug Enforcement Administration (DEA) and HHS allowed providers to prescribe controlled substances via telehealth, even if the patient is at home.	■					The DEA and HHS have the regulatory authority under the Ryan White Act to enable remote prescriptions of certain controlled substances, including MATs. Congress in the CAA 2023 directed the DEA to issue final rules on special registration for telehealth providers.
Qualifying providers can prescribe buprenorphine, a medication-assisted treatment (MAT), to new and existing patients with opioid use disorder based on a telephone evaluation. Source: DEA guidance, Substance Abuse and Mental Health Services Administration proposed rule					■	In December 2022, the Substance Abuse and Mental Health Services Administration (SAMHSA) released a Notice of Proposed Rulemaking to permanently allow patients to start buprenorphine in an opioid treatment program by telehealth without the required in-person physical examination first. SAMHSA said it will provide an interim solution if it is unable to finalize the rule before May 11.
Telehealth modes (smartphone and audio only) Audiovisual telephones: The HHS Office for Civil Rights is exercising enforcement discretion for popular audio-visual applications, such as FaceTime and Zoom, allowing HIPAA-covered health care providers to furnish telehealth services via audio-visual devices (i.e., smartphones). Source: OCR enforcement discretion notice	■					Congressional action would be needed to modify HIPAA to enable the permanent use of smartphone devices for telehealth.

Federal telehealth pandemic policy	Projected expiration					Method for extension or permanence
Medicare	End of PHE (May 11)	151 days post-PHE	End of CY 2023	End of CY 2024	Permanent policy	
High-deductible health plans Commercial insurers are able to provide telehealth below the deductible in high-deductible health plans. Source: CARES Act; CAA 2023						Congressional action is needed to further extend or make permanent this policy. Under CAA 2022, effective April 1, 2022, this flexibility was extended through December 31, 2022. Congress further extended this through December 31, 2024 under CAA 2023. Treasury may permit/ designate some telehealth health measures as preventive coverage allowable below the deductible.
Telehealth as an excepted benefit under ERISA The US Departments of Labor, HHS and the Treasury have adopted a nonenforcement policy that allows telehealth or remote care services provided by an employer to be treated as an excepted benefit. Source: FAQ						The departments are expected to notify plans when they end the nonenforcement period. Congressional action would be needed to make this flexibility permanent.

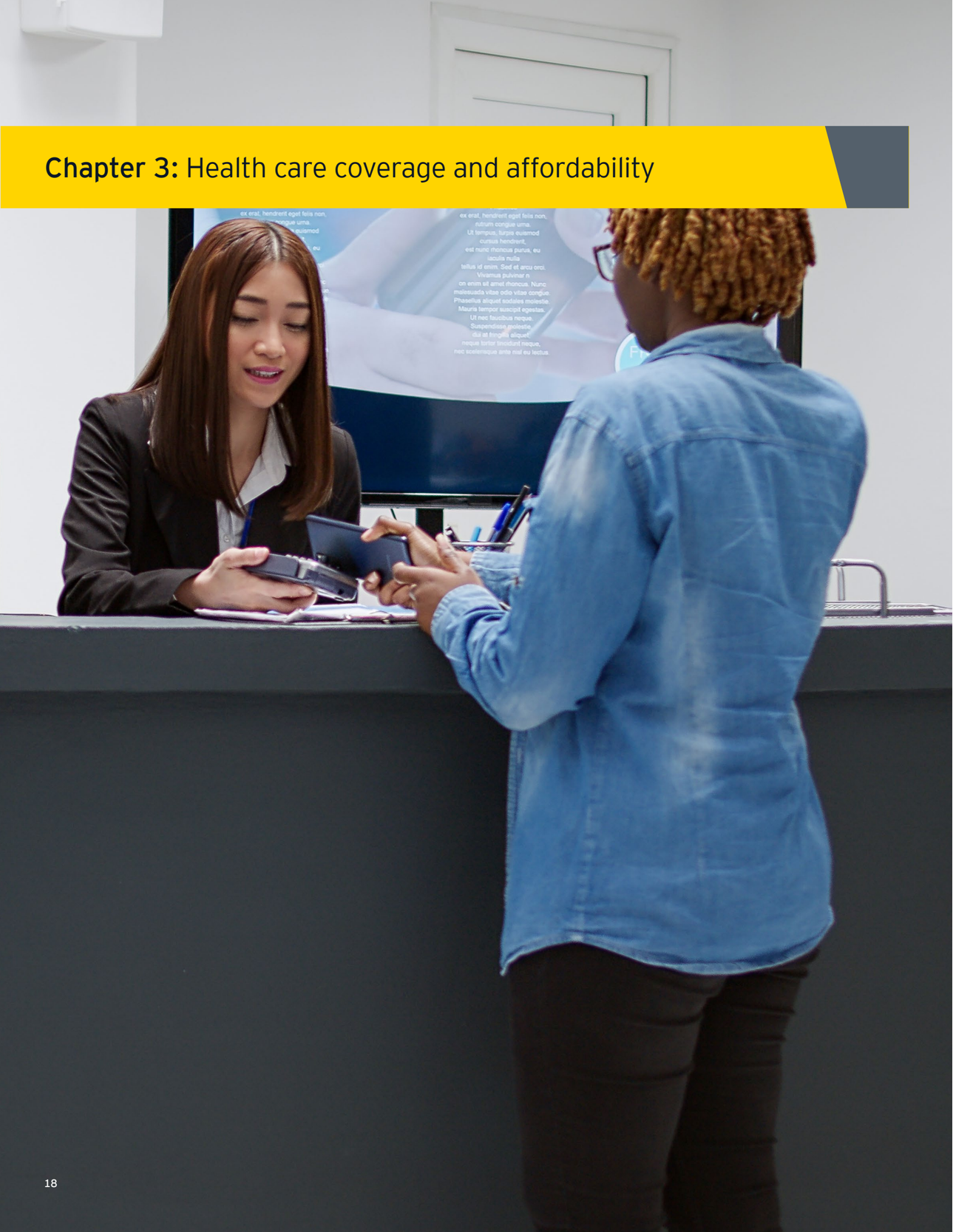
Telehealth waiver trends at the state level

Throughout the pandemic, all 50 states and Washington, DC declared states of emergency, which gave state governments the authority to expand telehealth access through Medicaid/CHIP and commercial insurers. CMS issued a toolkit encouraging state Medicaid agencies to adopt many of the agency's Medicare waivers.[12] And while many state agencies expanded their telehealth policies, some of those authorities are tied to their state declarations, which many states have since rolled back: As of February 2023, eight states still had emergency orders in place.[13]

States that wish to permanently keep some of the COVID-19-era telehealth policies generally have broad flexibility to determine whether to cover telehealth, which services to cover, the geographic regions in which telehealth may be used and how to reimburse providers for these services. In some cases, they may need to work with CMS to submit state plan amendments or apply for home and community-based services waivers (1915(c)). And some states have already moved to make certain telehealth changes permanent. For example, at least 21 states have implemented laws requiring payment parity between telehealth and in-person visits, and most states have permanently adopted Medicaid coverage for audio-only behavioral health consultations.

Many commercial insurers also voluntarily expanded access to telehealth visits at the start of the COVID-19 pandemic, authorizing no- or low-cost sharing for telehealth services and provider payment parity with in-person visits. But as the pandemic continued, many insurers began rolling back those reimbursement-related policies. In other cases, commercial insurers have made permanent changes to their reimbursement policies to cover certain routine virtual visits, audio-only visits and behavioral visits.[14]

Chapter 3: Health care coverage and affordability



The makeup of the health insurance market is poised to shift as Medicaid redeterminations ensue.

Throughout the COVID-19 pandemic, federal legislators and regulators have taken steps to pass new or modify existing health care coverage and affordability provisions to promote the stability and affordability of health care coverage due to concerns over employer-sponsored coverage losses and inadequate access to affordable coverage care. Those changes took aim at individuals and families in Medicaid, the individual market and the group market. For example, congressional Democrats and the Biden administration extended enhanced ACA subsidies for marketplace enrollees through 2025 under the IRA. In addition, on January 27, 2023, CMS announced a 16-month special exchange enrollment period to allow the estimated 5 million to 15 million individuals who could lose Medicaid coverage as part of the redetermination process an opportunity to enroll in a marketplace plan.[15]

Estimated Change in Medicaid Enrollees from FY 2022 to FY 2023, by Enrollment Scenario

Number of People Eligible for Marketplace Subsidies Before and After American Rescue Plan Act

Sources: Kaiser Family Foundation, "10 Things to Know About the Unwinding of the Medicaid Continuous Enrollment Provision," 11 January, 2023, Kaiser Family Foundation, "How the American Rescue Plan Act Affects Subsidies for Marketplace Shoppers and People Who Are Uninsured," 23 March, 2021.

Pandemic coverage policy	Current expiration			Potential impact
	During CY 2023	End of PHE (May 11)	Beyond 2023	
Enhanced federal Medicaid match FFCRA provided an increase of 6.2 percentage points (ppt) in the Federal Medicaid Assistance Percentage (FMAP), coupled with requirements to meet certain maintenance of eligibility (MOE) requirements.				The loss of the enhanced FMAP gives states a financial incentive to process redeterminations more quickly. The enhanced FMAP will be phased out over a nine-month period in 2023, declining to 5 ppt April 1, 2.5 ppt July 1, and 1.5 ppt October 1, before being eliminated on January 1, 2024. **Source:** CAA 2023
Medicaid continuous coverage requirement As part of criteria to receive the enhanced FMAP, states were not able to involuntarily disenroll beneficiaries or make it harder for families to enroll.				The continuous coverage requirements end March 31, 2023, meaning states can begin processing renewals. States have up to 12 months to initiate eligibility renewals and 14 months to finish processing renewals. Stakeholders are worried about mass disenrollment once states resume redeterminations. Disenrollment projections range from a low of 5.3 million to a high of 15 million, but actual disenrollment figures are likely to vary based on how states handle the transition. Source: CAA 2023

Pandemic coverage policy	Current expiration			Potential impact
	During CY 2023	End of PHE (May 11)	Beyond 2023	
ARPA enhanced subsidies ARPA temporarily extended subsidy eligibility for ACA marketplace enrollees who have incomes over 400% of poverty and increased the amount of financial assistance for people at lower incomes who were already eligible.				The enhanced subsidies will **expire at the end of 2025,** barring Congressional action. This could have a significant impact on affordability and enrollment as the Biden administration announced that the 2022 open enrollment period saw a 21% increase in coverage over 2021 with premium savings of more than $537 million per month due to the enhanced subsidies. Separately, the CBO and the Joint Committee on Taxation (JCT) estimate that if the ACA marketplace subsidies expire, enrollment levels will decline and return to the pre-ARPA baseline by 2024. **Source:** American Rescue Plan Act Inflation Reduction Act
Group market: COBRA eligibility ARPA subsidized 100% of COBRA premiums from April 1, 2021 through September 30, 2021. The Departments of Labor and Treasury also extended the retroactive COBRA election period.				The policy will **expire 60 days after the end of the President's national emergency declaration on May 11.** Employers will have to update notice requirements to reflect the end to the pandemic period and change in election deadlines. **Source:** Department of Labor COVID-19 Disaster Relief Notice

Chapter 4: Provider relief and flexibilities

As pandemic relief funds run dry and pre-pandemic budgetary cuts resume, providers should look to post-pandemic revenue streams, including boosting patient volumes and optimizing high-reimbursement services.

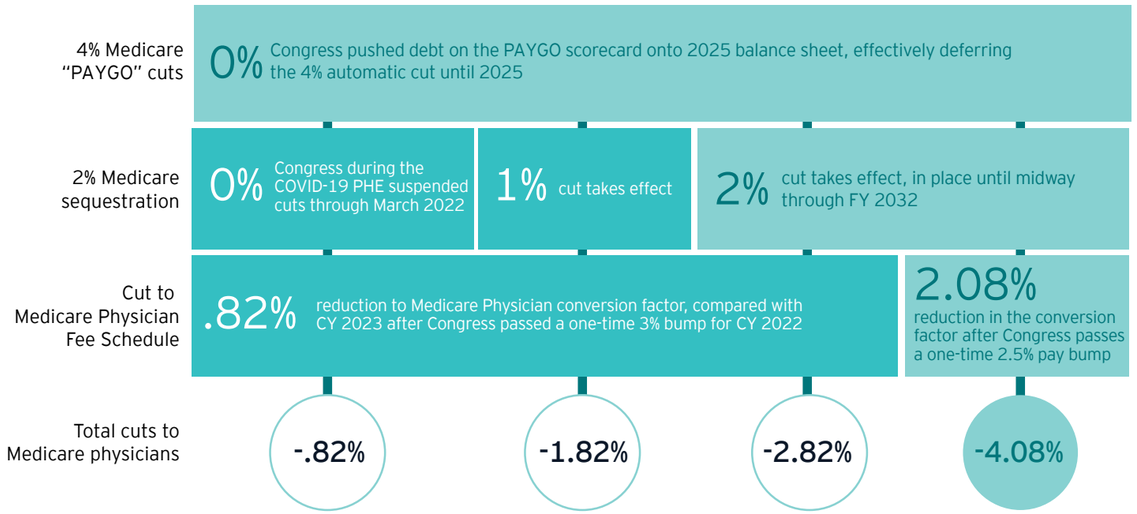
Scattered throughout pandemic relief packages and regulatory flexibilities, there was an influx of funding and other policies aimed at alleviating the financial impact of COVID-19 on hospitals and providers. However, much of this flexibility and funding has now run dry – or close to it – and other cuts that were staved off are coming back online.

COVID-19 relief funds that are set to end include:

- **Provider relief funding:** $178 billion in provider relief allocated through the Provider Relief Fund (established under the CARES Act) in addition to $8.5 billion in American Rescue Plan (ARP) rural funds to hospitals and other providers have nearly all been allocated, with slim chances of being reupped. Hospitals and other providers also benefitted from other pandemic programs such as the Paycheck Protection Program, which MedPAC estimated provided nearly $100 billion to health care providers.[16] CMS also expanded the COVID-19 Accelerated and Advance Payments (CAAP) Program, and Congress advanced additional flexibilities; however, CMS stopped accepting applications as of October 2020 for accelerated or advance payments as they relate to the COVID-19 PHE and has begun to recoup payments despite pressure from industry for additional delay.[17]
- **Increased payments for vaccines and treatments:** During the PHE, Medicare increased all inpatient reimbursement for COVID-19 patients by 20% during the PHE through April 14, 2022, created the New COVID-19 Treatment Add-on Payment (NCTAP) policy enabling eligible providers in the inpatient setting to receive additional payments for certain COVID-19 treatments, and increased reimbursement for COVID-19 vaccine administration.[18] For the uninsured and underinsured, a portion of the Provider Relief Funds were used to reimburse providers for administering COVID-19 vaccines to uninsured or underinsured individuals. CMS in the fiscal year 2022 Inpatient Prospective Payment System rule extended the NCTAP through the end of the year in which the PHE expires and the 20% add-on payment is expected to sunset with the PHE.[19]

In addition, providers throughout the pandemic have seen relief from statutory cuts to their Medicare payments, including 2% sequester cuts and annual payment bumps to the Medicare Physician Fee Schedule's conversion factor. However, some of those cuts have already been phased back in.

Across-the-board Medicare rate decreases



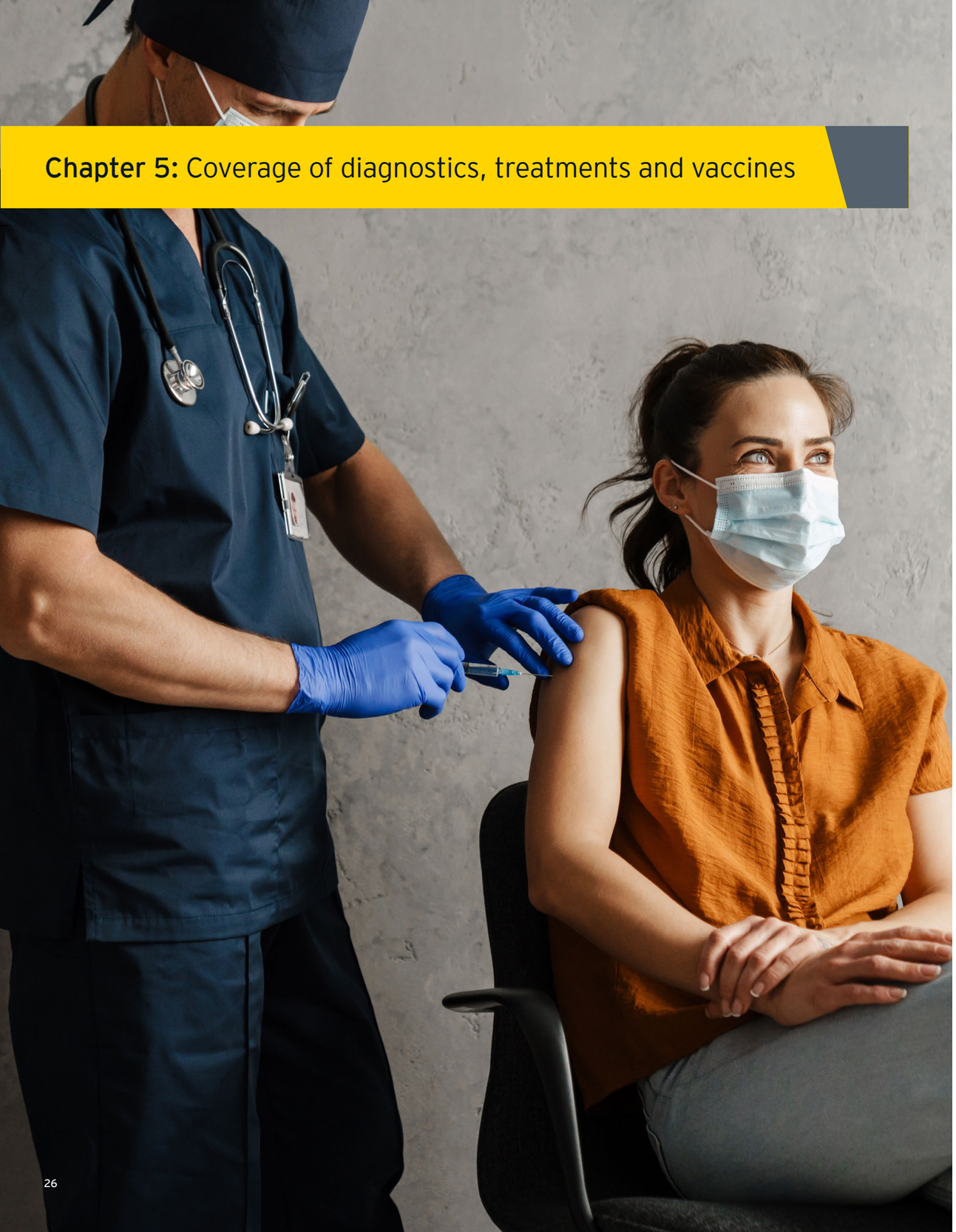
Sources: CAA 2023; CMS MLN Connects, 16 December 2023; MPFS CY 2023 final rule; Protecting Medicare and American Farmers from Sequester Cuts Act

Payment rule flexibilities and quality reporting

CMS implemented multiple flexibilities and measure suppression policies aimed at mitigating negative financial impacts due to COVID-19 and reducing the provider reporting burden during the PHE. CMS announced the agency will continue to use its Extreme and Uncontrollable Circumstances policy to allow clinicians, groups and virtual groups to submit an application requesting reweighting of one or more Merit-based Incentive Payment System (MIPS) performance categories for the 2023 performance year due to the COVID-19 PHE.[20]

Additionally, CMS has implemented a policy that enables the agency to suppress, or not use, certain quality measures that the agency believes may have been impacted by providers' COVID-19 response efforts. However, CMS through annual rulemaking has indicated that most measure suppression policies will expire for the 2023 performance year, indicating participants could be subject to all quality program requirements effective 2024. Below is a list of PHE-suppressed measures. In addition, for the Hospital Readmissions Reduction Program, CMS announced a new covariate adjustment for patient history of COVID-19 in the 12 months prior to admission for each of the six condition/procedure-specific measures beginning in 2024.

Quality program	Measures suppressed for 2023	Details
Hospital Readmissions Reduction Program (HRRP)	▸ 30-Day Pneumonia Readmissions Measure (NQF #0506) CMS will resume use of this measure for 2024, but it will exclude COVID-19 patients from measure numerators and denominators **Source:** FY 2023 Inpatient Prospective Payment System (IPPS) final rule	CMS calculates the measure's rate for the program year but zeroes out the weight when calculating scores.
Hospital Value-Based Purchasing (VBP) Program	▸ Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468) ▸ Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166) ▸ Five Healthcare-Associated Infection Safety Measures CMS will resume use of NQF #0468 in the 2024 performance year. **Source:** FY 2023 IPPS final rule	CMS would calculate all measure rates for FY 2023 and would exclude suppressed measures from final scoring. Based on this, CMS would give a neutral payment. CMS notes that its scoring methodology could impact providers' MIPS performance for the CY 2022 and 2023 performance periods and subsequent payment periods. CMS said it intends to resume using measure data for scoring and payment adjustments in the FY 2024 performance year.
Hospital Acquired Condition (HAC) Reduction Program	▸ Excluded all care data submitted during CY 2020, Q1-2 for two performance years ▸ Five CDC National Healthcare Safety Network health care-associated infection (HAI) measures for CY 2020, Qs 3-4 ▸ PSI-90 data **Source:** FY 2023 IPPS final rule	Hospitals will not receive a penalty for FY 2023 or a total HAC score.
Skilled Nursing Facility (SNF) Value-Based Purchasing Program	30-Day All-Cause Readmission Measure (SNFRM) **Source:** FY 2023 SNF Prospective Payment System Final Rule	For FY 2022, CMS assigned all SNFs a performance score of 0, ranking all facilities equally. For FY 2023, measure performance will be publicly reported but will not impact payment.
End-Stage Renal Disease Quality Incentive Program	▸ Standardized Hospitalization Ratio (SHR) clinical measure ▸ In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure ▸ Long-term Catheter Rate clinical measure ▸ Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure ▸ Kt/V Dialysis Adequacy Comprehensive clinical measure ▸ Standardized Fistula Rate clinical measure **Source:** CY 2022 End Stage Renal Disease Prospective Payment System final rule, fact sheet	CMS will not score the suppressed measures for PY 2023 but will provide confidential feedback reports to facilities on their measure rates, which will be based on 2019 data. CMS will also publicly report the suppressed data with caveats related to the PHE.



Chapter 5: Coverage of diagnostics, treatments and vaccines

Providers relying on COVID-19 treatments under EUA should begin to think through post-PHE treatment plans, while consumers will need to familiarize themselves with their insurer's cost-sharing policies related to COVID-19.

Emergency use authorization

EUA authority allows the FDA to facilitate availability and unapproved uses of medical countermeasures (MCMs) needed to prepare for and respond to public health, military and domestic emergencies involving chemical, biological, radiological and nuclear (CBRN) agents, including emerging infectious disease threats.[21] Throughout the PHE, the FDA has issued hundreds of EUAs for COVID-19 tests and treatments for use before formal FDA approval, as well as four COVID-19 vaccines.

As of December 2022, the FDA has approved two COVID-19 vaccines (Pfizer-BioNTech's Comirnaty and Moderna's Spikevax) and three drugs (the antiviral drug Veklury and the immune modulators Olumiant and Actemra) to treat COVID-19 in certain populations. The FDA maintains a full list of COVID-19 approved and authorized vaccines, treatments and medical devices.[22] the FDA in recent guidance indicated the end of the PHE will not impact existing EUAs or the FDA's ability to authorize new products and devices under emergency use.[23] Congress in the CAA 2023 will allow Medicare Part D to cover oral antiviral drugs granted EUAs through December 31, 2024.

Cost-sharing and coverage provisions

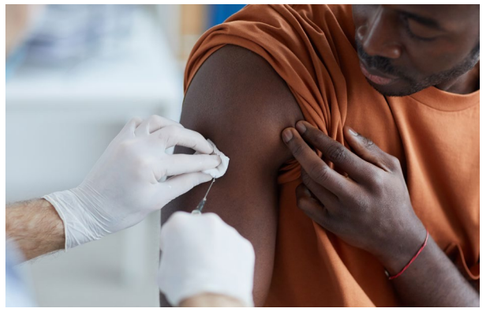
Throughout the pandemic, the federal government has purchased COVID-19 tests, treatments and vaccines and made them available to individuals at no cost, regardless of their insurance status through pharmacies, community health centers, federal sites, and allocations to states and localities. The availability of these government-purchased supplies has been instrumental in supporting large-scale testing and vaccination efforts and enhancing access to underserved communities.

In addition, the Health Resources and Services Administration (HRSA) oversees a program called the COVID-19 Uninsured Program (UIP) to reimburse providers for testing, treatment and vaccines for uninsured patients. However, funding for the uninsured program has run dry, as Congress declined to pass additional COVID-19 relief packages. The HRSA stopped accepting claims for testing and treatment on March 22, 2022, and claims for vaccine administration at on April 5, 2022, due to a lack of sufficient funds.[24] In addition, Ashish Jha, the White House's COVID-19 Response Coordinator, in February 2023 said the federal government could stop providing no-cost access to COVID-19 treatments and vaccines as soon as summer 2023.[25]

The lack of new federal funding for COVID-19 vaccines and treatments and the looming end to the PHE will mark a shift from government to commercial in terms of coverage and spending. It's expected that COVID-19 vaccines will continue to be available at no cost to those with public and private insurance, but cost sharing is likely to return for COVID-19 treatments and tests. The CAA 2023 includes a provision to ensure Medicare Part D temporarily covers oral antiviral treatments beyond the PHE, even if they are only available through EUAs. However, those treatments may not be available to those with commercial coverage temporarily because generally plans cannot cover treatments without FDA approval.

Below is an overview of coverage policies for Medicare, Medicaid and the commercial market.

Pandemic coverage policy	**Over-the-counter testing**	**Diagnostic testing**
Medicare	Medicare beneficiaries can get up to eight tests per calendar month from participating pharmacies and health care providers. This requirement is voluntary for Medicare Advantage plans. **Expiration:** End of the PHE.	Medicare Part B provides diagnostic COVID-19 testing and testing-related services with no cost sharing. Medicare Advantage plans are required to cover all Medicare Part A and Part B services, including COVID-19 lab tests. **Expiration:** End of the PHE.
Medicaid	Medicaid covers at-home COVID-19 testing without cost sharing. **Expiration**: Last day of the first calendar quarter beginning one year after end.	Medicaid is required to cover COVID-19 testing and treatment services for enrollees with no cost sharing. **Expiration:** The last day of the first quarter that begins at least one year after the PHE ends.
Commercial market	Private insurers are required to cover up to eight FDA-authorized rapid at-home COVID-19 tests purchased over the counter. **Expiration:** End of the PHE.	Private insurers are required to cover COVID-19 testing without cost sharing and insurers are prohibited from requiring prior authorization for COVID-19 testing. Short-term limited-duration plans are exempt from this requirement but encouraged to do so. **Expiration:** End of the PHE.



Pandemic coverage policy	**Treatments**	**Vaccines**
Medicare	Medicare covers monoclonal antibody infusions authorized for use by the FDA under EUA and beneficiaries currently face no cost sharing for this treatment, which could change once the PHE ends. **Expiration:** Medicare could resume cost sharing on monoclonal antibody infusions at the end of the PHE. Congress allowed Medicare Part D to cover oral antiviral treatments for COVID-19 granted EUA through December 31, 2024; coverage will likely continue once they are approved.	Medicare will cover the COVID-19 vaccine under Part B with no cost sharing for the vaccine or its administration for Medicare beneficiaries in both traditional Medicare and Medicare Advantage plans. **Expiration:** None. The CARES Act added coverage of FDA-approved COVID-19 vaccines to Part B without cost sharing and the Inflation Reduction Act extended this to include Part D vaccines.
Medicaid	Medicaid is required to cover COVID-19 treatment services for most enrollees with no cost sharing. **Expiration:** The last day of the first quarter that begins at least one year after the PHE ends.	Medicaid must cover COVID-19 vaccines and administration for most enrollees with no cost sharing. States as of April 1, 2021 receive 100% federal matching payments for vaccine administration. **Expiration:** The IRA requires Medicaid and CHIP to cover all ACIP-recommended vaccines for adults, including COVID-19 vaccines, without cost sharing.
Commercial market	No special financial protections for COVID-19 treatment. Some insurers voluntarily waived cost sharing for COVID-19 treatment early in the pandemic. **Expiration:** No specific date. Many insurers have already begun to phase out these waivers.	Most private group and individual plans must cover the COVID-19 vaccine without cost sharing, and insurers are prohibited from requiring prior authorization. **Expiration:** No set date. Private insurers are likely to continue coverage because the vaccine is now recommended by the Advisory Committee on Immunization Practices (ACIP) and the Affordable Care Act requires insurers to cover ACIP-recommended vaccines without cost-sharing.

Chapter 6: Workforce and other flexibilities

Health care providers are facing a workforce shortage crisis and will need to ensure they have the staffing needed to support patient volumes once the PHE and associated flexibilities end.

Throughout the pandemic, CMS issued several blanket waivers and flexibilities for health care providers that include workforce staffing and training requirements to give providers the flexibility needed to care for both COVID-19 and non-COVID-19 patients. These flexibilities enabled advanced practice providers, such as physician assistants (PAs) and nurse practitioners (NPs), to operate at the top of their licenses and forgo certain training requirements that would take them away from patient care. While both CMS and states have made some changes to permanently expand the scope of practice for these providers, many of the flexibilities granted during the PHE will expire once the PHE ends on May 11, 2023.

Pandemic workforce policy	Current expiration
Top of license flexibilities	
CMS waived requirements that Medicare patients be under care of a physician, provided the waiver complies with state rules/laws.	End of PHE
CMS waived requirements for physicians to conduct "physician visits" in long-term care facilities (LTCFs), allowing visits to be performed by PAs and other qualified providers.	End of PHE
CMS waived requirements certified registered nurse anesthetists (CRNAs) be supervised by a physician, provided it complies with hospital policy/state rules or laws.	End of PHE
CMS waived requirements for physician supervision of NPs at RHCs and FQHCs provided it meets state law.	End of PHE
Provider credentialing/licensure	
CMS allowed providers whose privileges were set to expire to continue practicing at hospitals and new providers to practice prior to full approval.	End of PHE
CMS waived requirements that providers be licensed in the state they are performing a service in to qualify for Medicare payment.	End of PHE
Provider credentialing/licensure	
CMS waived federal requirements for CAH staffing and deferred to state law.	End of PHE
CMS allowed physicians at SNFs/LTCFs to delegate certain tasks and patient visits to PAs, NPs or clinical nurse specialists who meet state and federal requirements, provided the service being delegated is not prohibited by the facility or state law.	CMS originally tied waivers to the PHE; however, due to quality-of-care concerns at SNFs/LTCFs, the CMS ended the waiver early, effective May 7, 2022
Staffing/training requirements	
CMS removed the 50% requirement for RHCs to have an NP, PA or certified nurse-midwife available to furnish patient care.	End of PHE
CMS waived requirements for nursing staff to have a care plan for each patient and hospitals/critical access hospitals (CAHs) to have RN policies in place for outpatient departments.	Expires at end of PHE or state emergency plan
CMS waived federal minimum personnel qualifications for clinical nurse specialists at CAHs. Nurses must still meet state licensure requirements.	End of PHE
CMS waived certain nurse aide training requirements, including completing a state-approved nurse aide competency evaluation program.	CMS announced it will begin to roll back this policy in certain circumstances
CMS waived requirements for nurses to complete 75 hours of training within four months of beginning their jobs.	CMS ended this waiver effective June 7, 2022

In addition, CMS approved numerous waivers to give providers more flexibility in their Medicare payment and coverage requirements. For example, CMS waived the three-day prior hospitalization requirement for skilled nursing facility (SNF) stays for those Medicare beneficiaries who need to be transferred during the PHE. This flexibility will expire at the end of the PHE.

Chapter 7: The future of PHE flexibilities

The end of the PHE will have real financial, operational and compliance impacts for consumers, providers, payers, states and manufacturers. Congress and the Biden administration have expressed their intent to continue to re-examine many of the COVID-19 flexibilities put in place to see if there is evidence to support allowing those flexibilities going forward. For example, Congress and CMS are actively examining telehealth policies, ways to support mental health and the health care workforce coming out of the pandemic, and ways to bolster public health capacity and prepare for the next pandemic. But other areas are ripe for more regulation, such as long-term care facilities, given the spotlight shone on them throughout the pandemic. Even in an era of divided government, many of the issues and challenges are bipartisan in nature and are likely to demand continued evaluation and action from Congress.

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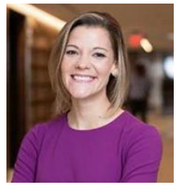

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