



COVID-19 Public Health Emergency Flexibilities

Updated April 3, 2023

Federal emergency powers generally stem from three key laws:

- The Public Health Service Act (PHSA);
- The National Emergencies Act (NEA); and
- The Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act).

[Section 319 of PHSA](#) allows the Department of Health and Human Services (HHS) Secretary to determine that “a public health emergency” exists and “take such actions as may be appropriate to respond to the public health emergency.” The Declaration of a public health emergency (PHE) triggers executive powers, including [authorizing](#) the Secretary of HHS to waive or modify certain requirements of Medicare, Medicaid, CHIP, HIPAA, and other provisions related to certification or licensing of health care providers, sanctions related to physician referrals, deadlines, and other penalties.

The NEA provides a framework to apply when the President seeks to leverage certain powers or authorities during a national emergency. Regarding healthcare authorities, to establish waivers under Section 1135 of the Social Security Act, the HHS Secretary must declare a PHE **and** the President must declare a national emergency under the NEA.

The Stafford Act provides emergency protective measures for activities taken in response to the COVID-19 outbreak, including FEMA assistance, use of the National Guard, law enforcement and other measures.

- A PHE under the PHSA was [declared](#) in January 2020 as a result of confirmed cases of 2019 Novel Coronavirus (COVID-19). Since then, the PHE Declaration has been renewed quarterly, and was most recently renewed on February 11, 2023.
- In March 2020 a national emergency was declared pursuant to sections 201 and 301 of the NEA and section 1135 of the Social Security Act, and under Section 501(b) of the Stafford Act. In February 2023, the national emergency under NEA and Stafford were again [extended](#).
- On January 30, 2023 a White House [Statement of Administration Policy](#) announced **May 11, 2023** as the anticipated end date for the COVID-19 national emergency, Stafford Act, and PHE declarations.
- On March 29, 2023, Congress enacted [H.J.Res.7](#), which terminates the declaration under the NEA, effective upon the signature of the President, who has ten days to sign the resolution into law.
- On March 31, 2023 [CMS issued a FAQ](#), clarifying that the end to the COVID-19 National Emergency as per H.J. Res 7 does not impact current operations at HHS, and that HHS will retain the May 11 expiration of the federal PHE for COVID-19 (it had initially appeared that the end of the national emergency might end all 1135 powers, but CMS determined that it can leverage Stafford Act powers to continue them).

Below, we have compiled a list of key flexibilities authorized by HHS or the CMS using emergency authority or newly created by Congress over the course of last three years. Many of the flexibilities are tied to the PHE and the national emergency declarations and will conclude with the termination of either. The exceptions are any provisions with differing timelines as mandated by statute, such as those related to telehealth, and any policy changes implemented through interim final rules or administrative discretion.

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Telemedicine	Section 1135 Waiver Authority	<i>Overview of 1135</i>	<p>When the President declares a disaster or emergency under the Stafford Act or National Emergencies Act and the HHS Secretary declares a public health emergency under Section 319 of the Public Health Service Act, the Secretary is authorized to take certain actions in addition to his/her regular authorities. For example, under section 1135 of the Social Security Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and CHIP requirements to ensure:</p> <ul style="list-style-type: none"> - Sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods - Providers who give such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). 	<p>CMS Overview of Section 1135 Waivers; CRS Report</p> <p>CMS released clarifying language that 1135 waivers will remain in place until May 11.</p>
		<i>Medicare: Waiver of Originating Site for Telehealth Reimb.</i>	<p>Section 1135(b)(8), as added by the CARES Act, gives the Secretary the authority to waive requirements of 1834(m) for telehealth services furnished in any emergency area (or portion of such area) during any portion of any emergency period.</p> <p>Note: The Consolidated Appropriations Act of 2022 (P.L. 117-103) amended the current originating site definition and expanded it to mean any site in the United States at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system (without geographic restriction). There is also no facility fee.</p>	<p>Extended through December 31, 2024 as a result of the Consolidated Appropriations Act (CAA), 2023.</p> <p>Statute; HHS List of Telehealth flexibilities</p>
		<i>Medicare: Qualifying Providers</i>	<p>CMS waved the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services.</p> <p>Note: The Consolidated Appropriations Act of 2022 (P.L. 117-103) temporarily added qualified occupational therapists, physical therapists, speech-language pathologists, and audiologists as eligible providers to provide telehealth services.</p>	<p>Extended through December 31, 2024 as a result of the CAA 2023.</p> <p>Guidance; Billing Guidance</p>
		<i>Medicare: Payment Rates</i>	<p>Medicare pays the same amount for telehealth services as it would if the service were furnished in person. The telehealth waiver will be effective until the end of the PHE declared by the Secretary of HHS on January 31, 2020. Billing for the expanded Medicare telehealth services, as well as for the telephone assessment and management, telephone, evaluation and management services, and additional flexibilities for communications technology-based services (CTBS) are effective beginning March 1, 2020, and through the end of the PHE.</p>	<p>Will be extended through December 31, 2024 as a result of the CAA 2023.</p> <p>Tied to the PHE. Billing Guidance</p>
		<i>Medicare: Covered Services</i>	<p>CMS notes that under the emergency declaration and 1135 waivers, Medicare telehealth services include many services that are normally furnished in-person. These services are described by HCPCS codes and paid under the Physician Fee Schedule. These services may be provided to patients by physicians and certain non-physician practitioners regardless of the patient's location.</p>	<p>Extended through December 31, 2024 as a result of the CAA 2023.</p>

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				Tied to the PHE. Billing Guidance
		Medicare: Audio Only	<p>CMS waived the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone E&M services, and behavioral health counseling and educational services</p> <ul style="list-style-type: none"> Medicare payment for the telephone evaluation and management visits (CPT codes 99441-99443) is equivalent to the Medicare payment for office/outpatient visits with established patients effective March 1, 2020. After the PHE ends, the Consolidated Appropriations Act, 2023 provides for an extension for this flexibility through December 31, 2024. When clinicians have furnished an evaluation and management (E/M) service that otherwise would have been reported as an in-person or telehealth visit, using audio only technology, practitioners have been able to bill using these telephone E/M codes provided that it is appropriate to furnish the service using audio-only technology and all of the required elements in the applicable telephone E/M code (99441-99443) description are met. After the PHE ends, the Consolidated Appropriations Act, 2023 extends availability of the telehealth services that can be furnished using audio-only technology through December 31, 2024. 	<p>Extended through December 31, 2024 as a result of the CAA 2023.</p> <p>Clinician guidance; General guidance; Billing FAQ</p>
		Medicare: Direct Supervision	<p>CMS notes that for the duration of the PHE, it has revised the definition of direct supervision to include a virtual presence through the use of interactive telecommunications technology, for services paid under the Physician Fee Schedule as well as for hospital outpatient services. The revised definition of direct supervision also applies to pulmonary, cardiac, and intensive cardiac rehabilitation services during the PHE. Additionally, CMS changed the supervision requirements from direct supervision to general supervision, and to allow general supervision throughout hospital outpatient non-surgical extended duration therapeutic services. General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. General supervision may also include a virtual presence through the use of telecommunications technology but CMS notes that even in the absence of the PHE general supervision could be conducted virtually, such as by audio-only telephone or text messaging. The changes to supervision rules are effective for services beginning March 1, 2020, and last for the duration of the COVID-19 Public Health Emergency.</p> <p>In the 2023 PFS, CMS noted that this flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends. Additionally, CMS notes that it plans to continue to gather information on this topic. Additional guidance can be found here.</p> <ul style="list-style-type: none"> <i>Special provision for teaching physicians:</i> After the PHE, only teaching physicians in residency training sites located outside of a metropolitan statistical area may meet the presence for the key portion requirement through audio/video real-time communications technology. After the PHE, teaching physicians can bill for levels 4-5 of an office/outpatient evaluation and management (E/M) visit 	<p>Still a temporary flexibility, but extended through CY2023 through the PFS.</p> <p>Billing Guidance</p> <p>Teaching Hospital Guidance</p>

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			<p>furnished by residents in these primary care centers only when the teaching physician is physically present for the key portion of the service.</p> <ul style="list-style-type: none"> <i>Special provision for behavioral health:</i> In the 2023 PFS, CMS finalized its proposal to allow general supervision (including through telehealth) under the incident-to billing regulation for behavioral health services. <i>Special provisions for CPT Code 99211</i> – CMS specified that the level one E/M visit can be billed when clinical staff assess a patient and collect a specimen for a COVID-19 diagnostic test for both new and established patients. After the PHE, the usual requirement for billing the level one E/M code (when clinical staff perform services incident to the services of the billing physician or practitioner for an established patient) apply (2/1/2023 Physician Guidance). 	<p>Permanent</p> <p>At this time, we believe the Special provisions for 99211 end with the PHE in May</p>
		Medicare: Established Patient Req.	<p>To the extent the 1135 waiver requires an established relationship, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency.</p> <p>CMS will make payments for telehealth services furnished to both new and established patients for the duration of the PHE.</p> <p>Starting March 1 and for the duration of the PHE, RPM services can be furnished to both new and established patients. CMS ordinarily requires an initiating visit for RPM services, similar to other care management services, but this requirement may be satisfied via a telehealth visit. Regardless, for the duration of the PHE, CMS is not requiring patients to be established patients in order to receive RPM services. Patients that receive RPM services can be established or new. Upon termination, clinicians must once again have an established relationship with the patient prior to providing RPM services (2/1/2023 Physician Guidance).</p>	<p>Tied to PHE, ends May 11, 2023. Fact Sheet; Billing Guidance</p>
		Medicare: Provider Address/ Enrollment	<p>CMS waived requirements to allow physicians and other practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. The waiver will continue through December 31, 2023.</p> <p><u>Care Compare</u> - Providers who have concerns with their practice location information being displayed publicly can contact Care Compare at: QPP@cms.hhs.gov to provide an alternate address or have their home address suppressed. This is a temporary approach.</p> <p>Moving forward, CMS is in the process of updating CMS-8551 enrollment forms to allow providers to indicate a clinical, administrative, or home address location -- enabling segmentation of that information that should not be disclosed publicly (e.g. via Physician Compare).</p>	<p>The waiver will continue through December 31, 2023. Guidance</p>
		Medicare: Acute Hospital Care at Home	<p>The CAA, 2023 amended and extended the Acute Hospital Care at Home Initiative, as currently authorized under CMS waivers and flexibilities, through December 31, 2024. This includes the waiver of telehealth requirements under the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, Strengthening Public Health Act of 2022, such that an originating site shall include the home or temporary residence of the individual.</p>	<p>Extended through December 31, 2024 as a result of the CAA 2023.</p>

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		Medicare: Licensure	<p>CMS waived requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS allowed licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area. <i>Note that this provision does not change state law requirements – many of which have reverted to pre-pandemic status.</i></p> <p>CMS has determined that, upon termination, CMS regulations will continue to allow for a total deferral to state law. Thus, there is no CMS-based requirement that a provider must be licensed in its state of enrollment (2/1/2023 Guidance).</p>	<p>Tied to PHE, ends May 11, 2023.</p> <p>Guidance</p>
	PREP Act	Licensure	<p>The 2005 Public Readiness and Emergency Preparedness Act (PREP Act) authorizes HHS to make declarations that provide immunity from liability in certain emergency circumstances. On December 3, 2020, HHS published Amendment 4 to the PREP Act to preclude state and local governments from enforcing more restrictive policies that keep “qualified persons” from administering countermeasures recommended by a PREP Act declaration.</p> <p>Specifically, this allows for interstate practice of telemedicine to improve public health outcomes in an emergency. This amendment provides liability protection when delivering specific COVID-19 related services, expands telehealth access, and makes it easier to treat and prevent COVID-19.</p> <p>PREP Act immunity is tied to the PREP Act Declaration, rather than the PHE Declaration, and the White House’s announcement therefore does not impact the protections offered under the PREP Act. While the PREP Act Declaration and its liability protections are effective until either (1) the PREP Act Declaration is formally revoked; or (2) October 1, 2024, whichever occurs first. See here for PREP Act guidance.</p>	<p>Extended through October 1, 2024 or the final day of the applicable PREP Act Declaration, whichever comes first.</p> <p>Notice of 4th Amendment</p>
	CARES Act & Enforcement Discretion	Pre-deductible Coverage of Telehealth for HDHP Plans	<p>Under the CARES Act, a high deductible health plan (HDHP) temporarily can cover telehealth and other remote care services without a deductible, or with a deductible below the minimum annual deductible otherwise required by law. Telehealth and other remote care services also are temporarily included as categories of coverage that are disregarded for the purpose of determining whether an individual who has other health plan coverage in addition to an HDHP is an eligible individual who may make tax-favored contributions to his or her HSA. Thus, an otherwise eligible individual with coverage under an HDHP may still contribute to an HSA despite receiving coverage for telehealth and other remote care services before satisfying the HDHP deductible, or despite receiving coverage for these services outside the HDHP.</p> <p>CMS will not take enforcement action against any health insurance issuer that amends its catastrophic plans to provide pre-deductible coverage for telehealth services, even if the specific telehealth services covered by the amendment are not related to COVID-19. This enforcement discretion will also apply for the period during</p>	<p>Extended through December 31, 2024 as a result of CAA 2023.</p> <p><i>CMS enforcement discretion ongoing.</i></p>

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			which either the COVID-19 public health emergency declaration or national emergency declaration is in effect. CMS would continue to take enforcement action against any health insurance issuer that attempts to limit or eliminate other benefits under a catastrophic plan to offset the costs of providing pre-deductible coverage for telehealth services.	
	Enforcement Discretion Enforcement Discretion	Telehealth as an Excepted Benefit	<p>On June 23, 2020, the Departments of Labor, HHS and Treasury jointly issued an FAQ pertaining to the Families First Coronavirus Response Act, the Coronavirus Aid, Relief, and Economic Security (CARES) Act and other health coverage issues. Specifically, it stated that the agencies would take a non-enforcement position for employers wishing to provide telehealth or other remote care services to employees ineligible for any other employer-sponsored group health plan for the duration of the PHE. This allowed employers to offer stand-alone telehealth benefits in addition to traditional health care plans, enabling workers such as seasonal and part-time workers to access telehealth benefits.</p> <p>The treatment of telehealth services as an excepted benefit is temporary and will expire at the end of the PHE on May 11, 2023 without action by Congress.</p>	<p>Tied to PHE, ends May 11, 2023.</p> <p>FAQ</p>
		HIPAA	<p>During the pandemic, Medicare-covered providers were able to use any non-public facing application to communicate with patients without risking any federal penalties, even if the application wasn't in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).</p> <p>The HHS Office for Civil Rights (OCR) exercised its enforcement discretion to not impose penalties for noncompliance with the regulatory requirements under the HIPAA Privacy, Security and Breach Notification Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. This flexibility will end at the end of the PHE on May 11.</p> <p>OCR has issued guidance to help health care providers and health care plans bound by HIPAA Rules understand how they can use remote communication technologies for audio-only telehealth post-COVID-19 public health emergency.</p>	<p>Tied to PHE, ends May 11, 2023.</p> <p>Guidance; OCR will maintain discretion through the PHE.</p>
		Cost-Sharing Waiver	<p>Ordinarily, if physicians or practitioners routinely reduce or waive costs owed by Federal health care program beneficiaries, including cost-sharing amounts such as coinsurance and deductibles, they would potentially implicate the Federal anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries.</p> <p>OIG issued a policy statement notifying providers that it will not enforce these statutes if providers choose to reduce or waive cost-sharing for telehealth visits during the COVID-19 PHE.</p>	<p>Tied to PHE, ends May 11, 2023.</p> <p>Policy Statement, Fact Sheet</p>
	CAA, 2022, CAA, 2023	Individual and Group Markets – Mid-Year Changes	Issuers in the individual and group markets are generally not permitted to modify a health insurance product mid-year. However, to facilitate the nation's response to COVID-19, CMS will 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, even if the specific telehealth services covered by the change are not related to COVID19.	<p>Tied to the PHE, ends May 11, 2023.</p> <p>Guidance</p>

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		Medicare: FQHCs and RHCs	CAA 2022 initially amended Section 1834(m)(8) of the Social Security Act (42 U.S.C. 1395m(m)(8)) to extend the CARES Act telehealth payment structure for federally qualified health centers (FQHCs) and rural health clinics (RHCs) for 151 days after the PHE ends. CAA 2023 extended this flexibility through December 31, 2024.	Extended through December 31, 2024 as a result of the CAA 2023.
		Medicare: In-person requirement for mental health	Section 1834(m)(7)(B)(i) of the Social Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is amended to delay the in-person requirements under Medicare for mental health services furnished through telehealth and telecommunications technology for 151 days after the PHE ends, until the day that is the 152 day after the end of the emergency period. In-person requirements for rural health clinics and federally qualified health centers shall not apply prior to the day that is the 152 day after the end of the PHE.	Extended through December 31, 2024, as a result of the CAA 2023.
	Other	Medicare: Hospice recert.	Section 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)) is amended to extend the CARES Act provision allowing for the use of telehealth to conduct face-to-face encounters prior to recertification of eligibility for hospice care during an emergency period for 151 days after the end of the PHE.	Extended through December 31, 2024 as a result of the CAA 2023.
	Other	Prescribing Controlled Substances	<p>While a prescription for a controlled substance issued by means of the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation (21 U.S.C. 829(e)), the Controlled Substances Act contains certain exceptions to this requirement. One such exception occurs when the Secretary of Health and Human Services has declared a public health emergency. On March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:</p> <ul style="list-style-type: none"> - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice; - The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and - The practitioner is acting in accordance with applicable Federal and State laws. <p>Additionally, qualifying practitioners can prescribe buprenorphine to new and existing patients with opioid use disorder based on a telephone evaluation</p> <p><i>Note that while this is currently a PHE flexibility, permanent statutory authority exists under the SUPPORT Act (Public Law 115-271, Section 3232) Rulemaking announced on March 1 that would end most flexibility. March 1, 2023 Notice of Proposed Rulemaking Summary</i></p>	<p>Controlled Substances Act authority tied to any public health service Act PHE – still ends on May 11, 2023.</p> <p>Information; Buprenorphine Guidance</p>
PREP Act Liability Protections	PREP Act	Liability Protections for Covered Counter-measures	The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims in-volving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration	Timing depends on the type of countermeasure. Some are extended through October 1,

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			<p>may be amended as circumstances warrant. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID-19. The Secretary has since made 10 amendments to the Declaration.</p> <p>The 1st amendment to the Declaration included NIOSH-approved respiratory protective devices as covered countermeasures, pursuant to the CARES Act’s amendments to the PREP Act.</p> <p>The 2nd amendment to the Declaration clarified that drugs, biological products, and devices that “limit the harm COVID-19 might otherwise cause” are covered countermeasures, and that the HHS Declaration reaches “all qualified pandemic and epidemic products defined under the PREP Act.”</p> <p>The 3rd amendment to the Declaration expanded the definitions of covered diseases and covered persons. First, HHS expanded the categories of disease representing a PHE to reach not just COVID-19, but also “other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom.” In particular, such “other diseases” include diseases resulting from “the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.” The amendment thus declares that pediatric vaccines (if licensed by FDA and recommended by the CDC’s Advisory Committee on Immunization Practices (ACIP)) are covered countermeasures. The amendment further identifies State-licensed pharmacists (and pharmacy interns acting under their supervision if the pharmacy intern is licensed or registered by his or her State board of pharmacy) as qualified persons under section 247d-6d(i)(8)(B) when the pharmacist orders and either the pharmacist or the supervised pharmacy intern administers ACIP-recommended vaccines to individuals ages three through 18 pursuant to certain requirements</p> <p>The 4th amendment to the Declaration states that the Declaration “must be construed in accordance with” the HHS advisory opinions, which are expressly “incorporate[d]” into the Declaration. It also made several changes to expand the scope of PREP Act immunity, including that the Declaration (1) covers “all qualified pandemic and epidemic products” within the meaning of the statute; and (2) may apply to claims based on not administering a covered countermeasure, such as when the countermeasure is in short supply. The 4th Amendment also adds a third covered means of distribution to extend liability protections to “additional private distribution channels.”</p> <p>The 5th, 6th, and 7th amendments sought to “expand the pool of COVID-19 vaccinators” beyond providers already licensed in a given state. The amendments accomplish this end by broadening the definition of “covered persons” who may serve as COVID-19 vaccinators in the HHS Declaration, and preempting state laws to the contrary.</p> <ul style="list-style-type: none"> - The 5th amendment authorizes any healthcare professional or other individual who holds an active license or certification permitting the individual to prescribe, dispense or administer vaccines to prescribe 	<p>2024; others are either October 1, 2024, or the final day of the applicable PREP Act Declaration, whichever comes first.</p> <p>Full list; Additional Information; Fact Sheet; CRS Summary</p>

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			<p>dispense, or administer COVID-19 vaccines. Additionally, any physician, APRN, RN, or LPN with an inactive or expired license may prescribe, dispense, or administer COVID-19 vaccines.</p> <ul style="list-style-type: none"> - The 6th amendment authorizes any federal government employee, contractor, or volunteer who prescribes, administered, delivered, distributes, or dispenses a covered countermeasure. - The 7th amendment clarifies that observers should be experienced in administering intramuscular injections, and adds additional categories of qualified persons covered under the PREP Act, including (1) health care professionals licensed by a state to administer vaccines, including outside their state of licensure; (2) members of uniformed services (such as the National Guard members) and certain authorized federal contractors, volunteers, and employees; (3) state-licensed midwives, paramedics, emergency medical technicians (EMTs), physician assistants, respiratory therapists, dentists, podiatrists, optometrists, and veterinarians; (4) physicians, registered and practical nurses, pharmacists, pharmacy interns, midwives, paramedics, EMTs, respiratory therapists, dentists, physician assistants, podiatrists, optometrists, and veterinarians whose licenses became inactive, expired, or lapsed within the previous five years; and (5) certain medical, nursing, pharmacy, dental, podiatry, optometry, veterinary, and other students under the supervision of a practicing health care professional. <p>The 8th amendment to the Declaration revises subsections (d) and (f) to clarify that qualified pharmacy technicians are Qualified Persons covered by the Declaration, and to expand the scope of authority for qualified pharmacy technicians to administer seasonal influenza vaccines to adults within the state where they are authorized to practice and for interns to administer seasonal influenza vaccines to adults consistent with other terms and conditions.</p> <p>The 9th amendment to the Declaration provides liability immunity to and expands the scope of authority for the types of providers who may administer COVID-19 therapeutics, including licensed pharmacists to order and administer select COVID 19 therapeutics to populations authorized by the FDA and for pharmacy technicians and pharmacy interns to administer COVID 19 therapeutics to populations authorized by the FDA when certain criteria are met.</p> <p>The 10th amendment to the Declaration adds subsection (j) to expand the scope of authority for licensed pharmacists to order and administer and qualified pharmacy interns to administer seasonal influenza vaccines across state lines, so long as they hold an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any state.</p>	
Coverage – COVID Testing	FFCRA	Testing – Medicare	<p>FFCRA Section 6002 waived cost sharing under the Medicare program for certain visits relating to testing for COVID-19. FFCRA section 6003 also provided coverage and waived cost sharing under the Medicare Advantage program for certain visits relating to testing for COVID-19.</p> <p>CMS issued regulations in April 2020 noting that an order from a treating physician is not required for COVID-19 testing to be covered under Medicare. Medicare Advantage plans are required to cover all Medicare Part A and Part B services, including COVID-19 testing. Medicare also covers antigen testing.</p>	<p>Tied to the § 319 PHE</p> <p>Regulations</p>

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			<u>Additionally</u> , clinical diagnostic testing, including testing for COVID-19 is covered at no cost under Part B. Beneficiaries in both FFS Medicare and MA pay no cost-sharing for at-home testing during the PHE.	
	ARPA, FFCRA	Medicaid/CHIP	<p>Section 6004 of FFCRA required Medicaid and CHIP programs to provide coverage for COVID-19 testing with no cost sharing.</p> <p>ARPA Sections 9811 and 9821 - APRA expanded this requirement, and requires state Medicaid and CHIP programs to cover a broad array of COVID-19 testing, including all types of U.S. Food & Drug Administration (FDA)-authorized COVID-19 tests, without cost-sharing obligations, for a period of time that began March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period. In meeting these ARP requirements, states must continue to apply normal third-party liability rules and may continue to apply utilization management techniques.</p> <p>ARPA also amended the Act to require coverage of additional testing for COVID-19 for individuals eligible for the optional Medicaid eligibility group – the optional COVID-19 testing group.</p> <p>ARPA sections 9811 and 9821 also amended sections 1916, 1916A, and 2103(e)(2) of the Act to specify that states cannot impose cost-sharing with respect to the COVID-19 testing coverage required under ARPA and described in sections 1905(a)(4)(F) and 2103(c)(11)(B). ARPA section 9811(a)(5) also amended section 1937(b) of the Act to require states to include the same COVID-19 testing coverage in Medicaid alternative benefit plans, without any deduction, cost-sharing, or similar charge.</p> <p>CMS interpreted the amendments made by sections 9811 and 9821 of ARPA to require states to cover both diagnostic and screening tests for COVID-19 (which includes their administration).</p>	<p>Until the last day of the first calendar quarter that begins one year after the end of the § 319 PHE</p> <p>Guidance</p>
	FFCRA, CARES	Testing – Group and Individual Market	<p>Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage, including grandfathered health plans, to provide benefits for certain items and services related to testing for the detection or the diagnosis of COVID-19, when those items or services are furnished on or after March 18, 2020, and during the PHE. Plans and issuers must provide this coverage without imposing any cost sharing requirements, prior authorization, or other medical management requirements.</p> <p>Section 3201 of the CARES Act amended section 6001 of FFCRA to include a broader range of diagnostic items and services, requiring plans and issuers to reimburse a provider that has a negotiated rate with the plan or issuer for COVID-19 diagnostic testing in an amount that equals the negotiated rate or for the cash price listed on a public website.</p> <p>CMS initially issued guidance in June 2020, stating that plans and issuers are required to cover COVID-19 test intended for in-home testing when the test is ordered by an attending health care provider. In January 2022, CMS issued guidance revising this position and stating that individuals who purchase OTC COVID-19 tests during the PHE will be able to seek reimbursement from their plan or issuer with or without an order or individualized clinical assessment by and attending health care provider.</p>	<p>Tied to the § 319 PHE</p> <p>Guidance</p>

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			See EBSA FAQs issued March 29, 2023	
	Administration	Testing – Medicare and Medicare Advantage	<p>CMS launched an initiative that provides payment directly to eligible pharmacies and other entities that are participating in this initiative to enable people with Medicare to get up to eight free over-the-counter COVID-19 tests a month.</p> <p>All Medicare beneficiaries with Part B will be eligible to get eight free over-the-counter COVID-19 tests per month through a new initiative, whether enrolled in a Medicare Advantage plan or not.</p> <p>As of April 4, 2022, this initiative adds to existing options for people with Medicare to access COVID-19 testing, including:</p> <ul style="list-style-type: none"> • Requesting free over-the-counter tests for home delivery at gov. Every home in the U.S. is eligible to order two sets of four at-home COVID-19 tests. • Access to no-cost COVID-19 tests through health care providers at over 20,000 testing sites nationwide. A list of community-based testing sites can be found here. • Access to lab-based PCR tests and antigen tests performed by a laboratory when the test is ordered by a physician, non-physician practitioner, pharmacist, or other authorized health care professional at no cost through Medicare. • In addition to accessing a COVID-19 laboratory test ordered by a health care professional, people with Medicare can also access one lab-performed test without an order and cost-sharing during the public health emergency. 	<p>Tied to the § 319 PHE</p> <p>Fact sheet; beneficiary information; reporting; interested pharmacies and health care providers</p>
Coverage – COVID Vaccine	CARES Act	Medicare	<p>Section 3713 of the CARES Act provides for coverage of an FDA-approved COVID-19 vaccine under Part B of the Medicare program and for Medicare Advantage without cost-sharing for the vaccine or its administration.</p> <p>CMS has issued regulations requiring no-cost Medicare coverage of COVID-19 vaccines that are authorized for use under an EUA but not yet licensed by the FDA.</p> <p>For CY2020 and CY2021, Medicare payment for the COVID-19 vaccine and its administration for beneficiaries enrolled in MA plans will be made through FFS. For CY2022 Medicare payment for the COVID-19 vaccine and its administration for beneficiaries enrolled in an MA plan will be made by the beneficiary’s MA plan. Medicare FFS won’t pay COVID-19 vaccine administration claims for MA beneficiaries vaccinated on or after January 1, 2022.</p>	<p>Tied to the § 319 PHE</p> <p>Guidance</p>
	IRA	Medicaid/CHIP	Section 11405 of the IRA requires Medicaid and CHIP programs to cover all ACIP-recommended vaccines for adults, including the COVID-19 vaccine, and vaccine administration without cost sharing as a mandatory Medicaid benefit.	Permanently authorized by the IRA for most populations.
	CARES Act	Group and Individual Market	Section 3203 of the CARES Act requires group health plans and health insurance issuers offering group or individual health insurance to cover without cost-sharing any qualifying COVID-19 preventive service, which includes an immunization that has in effect a recommendation from ACIP of the CDC.	Tied to the § 319 PHE

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			<p>CMS guidance notes that issuers of non-grandfathered group or individual health insurance coverage are required to cover without cost sharing the vaccine and its administration when provided by a network provider, and during the COVID-19 PHE, are also required to cover without cost sharing then vaccine and its administration when provided by and out-of-network provider.</p> <p>See EBSA FAQs issued March 29, 2023</p>	Guidance
Coverage – COVID Treatment	N/A	Medicare	<p>There were no new requirements put in place by COVID relief legislation for COVID treatment coverage. Medicare will cover treatment for inpatient and outpatient services for treatment of COVID-19. Medicare provides coverage for COVID therapeutics, as outlined in this guidance.</p> <p>Under the CAA 2023, Part D plans are now permitted to cover oral antiviral drugs available under EUA through December 31, 2024.</p>	<p>Part D Plan may offer antiviral drugs under EUA through December 31, 2024.</p> <p>Guidance</p>
	ARPA	Medicaid/CHIP	<p>Section 9811(a) of the ARP added a new mandatory Medicaid benefit at section 1905(a)(4)(F) of the Social Security Act (Act). Section 9821 of the ARP added the same mandatory benefit for all CHIP enrollees at section 2103(c)(11)(B) of the Act. Under these amendments, beginning March 11, 2021, state Medicaid programs and separate CHIPs are required to cover treatments for COVID-19, including specialized equipment and therapies (including preventive therapies). Additionally, under these amendments, beginning March 11, 2021, state Medicaid programs and separate CHIPs must cover the treatment of a condition that may seriously complicate the treatment of COVID-19, if otherwise covered under the state plan (or waiver of such plan, including a section 1115 demonstration) for individuals who are diagnosed with or presumed to have COVID-19 during the period such an individual has (or is presumed to have) COVID-19. Section 9811(a)(2) of the ARP amended the statutory language following section 1902(a)(10)(G) of the Act to require coverage of the same COVID-19-related treatment for individuals eligible for the Medicaid optional COVID-19 group (formerly referred to by CMS as the “optional COVID-19 testing group”) described at section 1902(a)(10)(A)(ii)(XXIII) of the Act.</p> <p>ARP sections 9811 and 9821 also amended sections 1916, 1916A, and 2103(e)(2) of the Act to specify that states cannot impose cost sharing with respect to the COVID-19-related treatment coverage that is required under the ARP and described at sections 1905(a)(4)(F) and 2103(c)(11)(B) of the Act. ARP section 9811(a)(5) also amended section 1937(b) of the Act to require states to include the same COVID-19-related treatment coverage in Medicaid alternative benefit plans, without any deduction, cost sharing, or similar charge.</p> <p>These coverage requirements and cost-sharing prohibitions generally end on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period</p>	<p>Until the last day of the first calendar quarter that begins one year after the end of the PHE.</p> <p>Guidance</p>
	N/A	Group and Individual Market	No current requirements in place for COVID-19 treatment coverage. Existing cost-sharing charged apply. Plans may voluntarily waive cost-sharing.	N/A

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Medicare Provider Waivers/Flexibilities	Section 1135/ Section 1812(f)	Medicare, Medicaid & CHIP	CMS has authority to establish blanket 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020 through the end of the emergency declaration.	Tied to PHE, ends May 11, 2023. <u>Guidance</u> including full list of Waivers
	Section 1135/ Section 1812(f)	Medicare - Skilled Nursing Facility (SNF)	<p>3-Day Prior Hospitalization. Using the authority under Section (f) of the Act, CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID-19. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period.</p> <p>Waive Pre-Admission Screening and Annual Resident Review (PASRR). CMS is waiving 42 CFR 483.20(k), allowing nursing homes to admit new residents who have not received Level 1 or Level 2 Preadmission Screening.</p> <p>Other Flexibilities Are Related to: Resident Roommates and Grouping; Resident Transfer and Discharge; Physician Services; Quality Assurance and Performance Improvement (QAPI); In-Service Training; Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities; and more. Note, some components of these waivers ended on 5/10/2021</p> <p>On April 7th, CMS <u>announced</u> it would begin ending SNF-related flexibilities in 30-day and 60-day periods of time, including the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.</p>	Tied to PHE, ends May 11, 2023. <u>Original guidance;</u> <u>April 2022 guidance</u>
	Section 1135	Medicare - Home Health Agencies (HHAs)	<p>Requests for Anticipated Payment (RAPs). CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.</p> <p>Reporting. CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below:</p> <ul style="list-style-type: none"> - Extending the 5-day completion requirement for the comprehensive assessment to 30 days. - Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE. <p>Initial Assessments. CMS is waiving the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review.</p> <p>Waive Onsite Visits for HHA Aide Supervision. CMS is waiving the requirements at 42 CFR §484.80(h), which require a nurse to conduct an onsite visit every two weeks.</p>	Tied to PHE, ends May 11, 2023. <u>Guidance</u>

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			<p>Allow Occupational Therapists (OTs), Physical Therapists (PTs), and Speech Language Pathologists (SLPs) to Perform Initial and Comprehensive Assessment for all Patients. CMS is waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered.</p> <p>12-hour Annual In-service Training Requirement for Home Health Aides. CMS is modifying the requirement at 42 CFR §484.80(d) that home health agencies must assure that each home health aide receives 12 hours of in-service training in a 12-month period.</p> <p>Detailed Information Sharing for Discharge Planning for Home Health Agencies. CMS is waiving the requirements of 42 CFR §484.58(a) to provide detailed information regarding discharge planning, to patients and their caregivers, or the patient’s representative in selecting a post-acute care provider by using and sharing data.</p> <p>Clinical Records. In accordance with section 1135(b)(5) of the Act, CMS is extending the deadline for completion of the requirement at 42 CFR §484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days (when requested by the patient).</p>	
	Section 1135	Medicare - Hospice	<p>Waive Requirement for Hospices to Use Volunteers. CMS is waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours).</p> <p>Comprehensive Assessments. CMS is waiving certain requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients.</p> <p>Waive Non-Core Services. CMS is waiving the requirement for hospices to provide certain noncore hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology.</p> <p>Waived Onsite Visits for Hospice Aide Supervision. CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks.</p> <p>Hospice Aide Competency Testing Allow Use of Pseudo Patients. 42 CFR 418.76(c)(1). CMS is temporarily modifying the requirement in § 418.76(c)(1) that a hospice aide must be evaluated by observing an aide’s performance of certain tasks with a patient.</p> <p>12-hour Annual In-service Training Requirement for Hospice Aides. 42 CFR 418.76(d). CMS is waiving the requirement that hospices must assure that each hospice aide receives 12 hours of in-service training in a 12-month period.</p>	<p>Tied to PHE, ends May 11, 2023.</p> <p><u>Guidance</u></p>

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			Annual Training. CMS is modifying the requirement at 42 CFR §418.100(g)(3), which requires hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required.	
	Section 1135	Medicare - ESRD Facilities	<p>Training Program and Periodic Audits. CMS is waiving the requirement at 42 CFR §494.40(a) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.</p> <p>Emergency Preparedness. CMS is waiving the requirements at 42 CFR §494.62(d)(1)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification.</p> <p>Ability to Delay Some Patient Assessments. CMS is not waiving subsections (a) or (c) of 42 CFR §494.80, but is waiving the following requirements at 42 CFR §494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility.</p> <p>Time Period for Initiation of Care Planning and Monthly Physician Visits. CMS is modifying two requirements related to care planning, specifically:</p> <ul style="list-style-type: none"> - 42 CFR §494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. - §494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. <p>Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation. CMS is waiving the requirement at 42 CFR §494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel.</p> <p>Home Dialysis Machine Designation – Clarification. The ESRD Conditions for Coverage (CFCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine.</p> <p>Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded. CMS authorizes the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID19 and the need to mitigate transmission among this vulnerable population.</p> <p>Dialysis Patient Care Technician (PCT) Certification. CMS is modifying the requirement at 42 CFR §494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national</p>	<p>Tied to PHE, ends May 11, 2023.</p> <p><u>Guidance</u></p>

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			commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. Transferability of Physician Credentialing. CMS is modifying the requirement at 42 CFR §494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. Expanding Availability of Renal Dialysis Services to ESRD Patients. CMS is waiving the following requirements related to Nursing Home residents: Furnishing Dialysis Services on the Main Premises.	
	Section 1135	Medicare - Ambulatory Surgical Centers (ASCs)	Medical Staff. 42 CFR 416.45(b). CMS is waiving the requirement at § 416.45(b) that medical staff privileges must be periodically reappraised, and the scope of procedures performed in the ASC must be periodically reviewed. Nursing Services. 42 CFR 42 CFR §482.23(b)(1). For ASCs enrolling as hospitals during the PHE as part of the Hospitals Without Walls Program, CMS is waiving the particular requirement at 42 CFR §482.23(b)(1), which requires the hospital to have a licensed practical nurse or registered nurse on duty at all times.	Tied to PHE, ends May 11, 2023. Guidance
	Section 1135	Medicare - Ambulance Services	Medicare Ground Ambulance Data Collection System. CMS is modifying the data collection period and data reporting period, as defined at 42 CFR § 414.626(a), for ground ambulance organizations (as defined at 42 CFR § 414.605) that were selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) and for ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626. Ambulance Treat in Place. Pursuant to authority granted under section 9832 of the American Rescue Plan Act of 2021, CMS is waiving the requirements under section 1861(s)(7) and section 1834(l) of the Act that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under Medicare regulations (as described in section 410.40 to title 42, Code of Federal Regulations (or successor regulations)) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the public health emergency described in subsection (g)(1)(B).	Tied to PHE, ends May 11, 2023. Guidance
	Section 1135	Medicare – DMEPOS	When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME Medicare Administrative Contractors (MACs) to have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician’s order, and new medical necessity documentation are not required.	Tied to PHE, ends May 11, 2023. Guidance
Medicare Provider Enrollment & Appeals	Section 1135	Medicare	Non-Waiver CMS Action: CMS has a toll-free hotline for physicians and non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges. - Allow licensed providers to render services outside of their state of enrollment.	Tied to the PHE, ends May 11, 2023. Guidance

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			<ul style="list-style-type: none"> - Allow physicians and other practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. As noted above, this waiver will continue through December 31, 2023. (Please note that the CMS authority for extending until December is unclear – but must not be under 1135) 	The location flexibility will continue through December 31, 2023. <u>Guidance</u>
	Section 1135	Medicare FFS, MA, and Part D	<p>CMS is allowing MACs and QICs in the FFS program pursuant to 42 CFR §405.942 and 42 CFR §405.962 (including for MA and Part D plans), as well as the MA and Part D IREs under 42 CFR §422.562, 42 CFR §423.562, 42 CFR §422.582 and 42 CFR §423.582, to allow extensions to file an appeal. CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 and the MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals.</p> <ul style="list-style-type: none"> - CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.910 and MA and Part D plans, as well as the MA and Part D IREs, to process an appeal even with incomplete Appointment of Representation forms as outlined under 42 CFR §422.561 and 42 CFR §423.560. However, any communications will only be sent to the beneficiary. - CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs, to process requests for appeals that do not meet the required element using information that is available as outlined within 42 CFR §422.561 and 42 CFR §423.560. - CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs under 42 CFR §422.562 and 42 CFR §423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied. 	Tied to PHE, ends May 11, 2023. <u>Guidance</u>
Permissive Actions for Managed Care Orgs	Enforcement Discretion	MA, Part D, and Medicare-Medicaid Plans	<p>On January 14, 2022, CMS informed MA Organizations, Part D sponsors, and Medicare-Medicaid Plans that they will extend the flexibilities discussed in the December 28, 2020, HPMS memo titled “<u>Contract Year 2021 Coronavirus Disease 2019 (COVID-19) Permissive Actions FAQ</u>” in contract year 2022. CMS will continue these flexibilities for the duration of the COVID-19 Public Health Emergency (<u>2/1/2023 MA and Part D Guidance</u>).</p> <p>Flexibilities discussed in the memo referenced above include:</p> <ul style="list-style-type: none"> - CMS will continue its policy of relaxed enforcement in connection with the prohibition on mid-year benefit enhancements. - CMS will continue to allow MAOs to waive or reduce enrollee cost-sharing for beneficiaries enrolled in their Medicare Advantage plans who are impacted by the outbreak as outlined in the May 22, 2020 HPMS memo, where the waiver or reduction in cost-sharing is tied to the COVID-19 outbreak. - CMS will continue to exercise its enforcement discretion regarding the administration of MAOs’ plan benefit packages as approved by CMS until it is determined that the exercise of this discretion is no longer necessary in conjunction with the COVID-19 outbreak. - CMS will continue to take these special circumstances presented by the COVID-19 outbreak into account when conducting MOC monitoring or oversight activities. 	A 3/24/23 HPMS memo indicated that CMS is ending enforcement discretion of plans’ benefit packages.

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			<ul style="list-style-type: none"> - CMS will continue to allow MAOs to implement a Rewards and Incentive Program for enrollees in connection with the COVID-19 outbreak, as previously stated in the set of questions and answers published on May 13, 2020 under the title “Updated Guidance for Medicare Advantage Organizations.” - CMS will continue its policy of relaxed enforcement in connection with actions Part D sponsors deem reasonable and necessary to keep their enrollees and employees safe and curb the spread of the virus, while still ensuring beneficiary access to needed Part D drugs (as referenced in the section titled “Additional Flexibilities” in the May 22, 2020 HPMS memo, “Information Related to Coronavirus Disease 2019 - COVID-19”) for the duration of the COVID-19 PHE. - CMS will continue its policy of relaxed enforcement in connection with prospective waivers or reductions of Part C and Part D premiums referenced in the October 15, 2020 HPMS memo, “Waiver of Premiums Related to COVID-19 Permissive Actions – Questions and Answers,” for the duration of the PHE. 	
COVID-19 Data Collection	CARES Act	Laboratory Reporting Requirements Related to COVID-19	<p>Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “[e]very laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). The statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting.</p> <p>In an effort to receive these data in the most efficient and effective manner, the Secretary is requiring that data elements be reported through existing public health data reporting methods, namely through reporting to state, territorial, local, and Tribal (STLT) public health departments as described in this guidance. As a guiding principle, data must be sent to STLT health departments using existing reporting channels to ensure rapid public health response by those departments (in accordance with STLT law, policies, and procedures). This reporting should be conducted concurrent to test results being shared with an ordering provider or patient, as applicable. HHS acknowledges that reporting laboratories rely on information they receive from ordering health care providers with patient specimens, as laboratories do not typically interact with patients. To enable and effectuate the purpose of § 18115(a), HHS strongly encourages ordering providers to collect and transmit the required data elements to laboratories with test orders.</p>	Tied to the § 319 PHE ; HHS guidance
	Section 1135	Hospital Reporting Requirements Related to COVID-19	CMS released regulatory requirements for all hospitals and critical access hospitals (CAHs) at 42 C.F.R. §§482.42(e) and 485.640(d), respectively, to report information in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID-19. Failure to report the specified data needed to support broader surveillance of COVID-19 may lead to the imposition of the remedy to terminate a provider’s participation from the Medicare and Medicaid programs.	Tied to PHE, ends May 11, 2023. CMS regulatory language
340B Status	Consolidated Appropriations Act of 2022	340B Eligibility Exceptions due to COVID-19 PHE	<p>The Consolidated Appropriations Act of 2022 was signed into law on March 15, 2022. Section 121 of the law permits certain hospitals to be reinstated into the 340B Drug Pricing Program if they meet the following conditions:</p> <ul style="list-style-type: none"> • The hospital must be classified as a: <ul style="list-style-type: none"> ○ disproportionate share hospital, ○ sole community hospital, ○ rural referral center, 	Ends December 31, 2022; HRSA notice

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			<ul style="list-style-type: none"> ○ children's hospital, or ○ free standing cancer hospital. • The hospital must have been terminated from the 340B Program due to an inability to meet the statutorily-required disproportionate share adjustment (DSH percentage) during Medicare cost reporting periods beginning October 1, 2019 and ending no later than December 31, 2022. • The hospital's termination must have been as a result of actions taken by or other impact on the hospital in response to, or as a result of, the COVID-19 Public Health Emergency (PHE). • The hospital must have been a covered entity on January 26, 2020 (i.e., the day before the first day of the COVID-19 PHE). 	
Medicaid Section 1115 Waivers	Section 1115 of the Social Security Act	Waiver Authorities	<p>During the PHE, states may request emergency 1115 flexibility for the following circumstances:</p> <ul style="list-style-type: none"> - Permit the state to target services on a geographic basis that is less than statewide - Vary amount, duration, and scope of services based on population needs and allow states to triage access to LTSS based on highest need - Waive requirement for in-person hearings for managed care appeals and instead allow beneficiaries to provide testimony in writing, by phone, or by video/virtual communication - Restrict beneficiary choice to a limited network of telehealth and mobile testing providers - Provide COVID-19 testing in school settings through the state's fee-for-service delivery system rather than through managed care 	<p>Will expire no later than 60 days after the end of the PHE. States must complete a final monitoring and evaluation report one year after the demonstration ends.</p> <p>Section 1115 demonstration opportunity and application template and approved 1115 waiver applications from the Medicaid.gov COVID-19 Section 1115 Demonstrations page</p>
		Expenditure Authorities	<ul style="list-style-type: none"> - Allow for self-attestation or alternative verification of individuals' eligibility (income and assets) and level of care to qualify for LTSS - Provide long-term care services and supports for impacted individuals even if services are not timely updated in the plan of care, or are delivered in alternative settings - Ability to pay higher rates for HCBS providers in order to maintain capacity - The ability to make retainer payments to certain habilitation and personal care providers to maintain capacity during the emergency - Allow states to modify eligibility criteria for LTSS - The ability to reduce or delay the need for states to conduct functional assessments to determine level of care for beneficiaries needing LTSS - Extend reassessment, reevaluation, and/or monitoring due dates for HCBS - Adjust assessment requirements for - Not allow visitors at any time to minimize spread of infection (for settings added after 3/17/14) - Temporarily modify person-centered plan development process - Add electronic and/or verbal method of document signing - Suspend data collection for performance measures other than health and welfare - Temporarily modify incident reporting requirements, medication management, or other participant safeguards to ensure individual health and welfare and account for emergency circumstances - Allow covered rehabilitative services to be provided in temporary residential settings - Suspend minimum and/or maximum hour/day limits for substance use disorder treatment services (intensive outpatient and/or residential, including IMDs) 	

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Policy Area	Authority	Flexibility	Original Authorizing Language/Description	Timing /Notes
			<ul style="list-style-type: none"> - Modify rate setting and interim payment methodologies in delivery system reform waiver component - Extend day and/or dollar limits for inpatient hospital stays related to COVID-19 Cover EPSDT dental services provided to beneficiaries who turned 21 on or after March 1, 2020 	
Medicaid Section 1135 Waivers	<u>Section 1135</u>	Provider Qualification & Enrollment	<p>During the PHE, states may request 1135 waiver flexibility for the following circumstances:</p> <ul style="list-style-type: none"> - Permit out-of-state providers with equivalent licensing in another state to provide care to another state's Medicaid enrollee impacted by the emergency. - Allow service provision in alternative settings, including unlicensed facilities. - Modify clinic facility requirements to allow services to be provided from practitioner's location via telehealth and/or in alternative settings, such as beneficiaries' homes, outdoors, schools, or other community-based locations. <p>The Secretary of the Department of Health and Human Services (HHS) ability to use 1135 waivers will end along with the declared national emergency.</p> <ul style="list-style-type: none"> - During the PHE, CMS issued <u>guidance</u> to states encouraging them to use existing authority to expand access to telehealth services under their Medicaid and CHIP programs. However, in a <u>fact sheet</u>, shared alongside a letter to Governors, HHS Secretary Becerra clarified that "this flexibility was available prior to the COVID-19 PHE and will continue to be available after the COVID-19 PHE ends." 	<p>Tied to PHE, ends May 11, 2023.</p> <p>Medicaid.gov <u>Section 1135 COVID-19 Request Template and Guidance</u>, approved 1135 waiver applications posted on the <u>Federal Disaster Resources</u> page of Medicaid.gov.</p>
		Prior Auth.	<ul style="list-style-type: none"> - Suspend FFS prior authorizations - Require FFS providers to extend pre-existing prior authorizations 	
		Appeals	<ul style="list-style-type: none"> - Allow managed care enrollees to bypass health plan appeal and go directly to fair hearing - Give enrollees >120 days (MCO appeals) or >90 days (FFS appeals) to request state fair hearing - Extend timeframe for enrollees to request that benefits continue while a state fair hearing or managed care appeal is pending - Allow 2 possible extensions up to 90 days each for health plan to collect additional info to make initial service authorization decisions favorable to enrollee, provided that health plan provides services while decision is pending and does not seek reimbursement from enrollee if authorization is ultimately denied - Extend timeframe for enrollee to file an internal health plan appeal from 60 to 120 days following the receipt of an adverse benefit determination Allow health plans to request a 30-day extension of time to resolve standard appeals, if in the enrollee's interest 	
		Long Term Services & Supports	<ul style="list-style-type: none"> - Suspend pre-admission screening and annual resident review (PASRR) level I & II for 30 days - Extend minimum data set (MDS) authorizations for NFs and SNFs - Temporarily allow HCBS to be provided in settings that have not been determined to meet home and community-based settings rule criteria when individual must be relocated to alternative setting to ensure continuation of services - Allow verbal consent in lieu of written signatures for HCBS person-centered service plans - Extend reassessment, reevaluation, and/or monitoring due dates for HCBS - Adjust assessment requirements for HCBS - Allow case management entities to be HCBS direct service providers 	

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			<ul style="list-style-type: none"> - Permit payment for state plan personal care services rendered by family caregivers or legally responsible relatives or representatives - Allow face-to-face encounter for Home Health services to take place up to 12 months after the start of service 	
		Reporting & Oversight	<ul style="list-style-type: none"> - Modify deadlines for OASIS and MDS assessment & transmission - Suspend aide supervision requirement by RN for HH agencies - Suspend supervision of hospice aides by RN 	
		State Plan Amendment Flexibilities	<ul style="list-style-type: none"> - Modify submission deadline and public notice timeframe for SPAs for the new medication-assisted treatment benefit required by the SUPPORT Act so that states may submit these SPAs by 3/31/21 with an effective date of 10/1/20 - Modified deadline for submission of COVID-19-related SPAs effective in a previous calendar quarter 46 states - Waive public notice for submission of emergency-related SPAs and/or 1115 waivers - Modify tribal consultation timeframe for submission of emergency-related SPAs and/or 1115 waivers 	
Medicaid Appendix K	Section 1915 (c) Waiver Appendix K	Eligibility	<p>During the PHE, states may use Appendix K waiver flexibility for the following circumstances:</p> <ul style="list-style-type: none"> - Prioritize offering waiver services to individuals presumed COVID-19 positive or quarantined, or to those in inpatient facility stays in COVID-19 ""hot spots"" - Temporarily increase cost limits for entry into waiver - Temporarily modify additional targeting - Temporarily allow individuals to maintain waiver eligibility without receiving services or fulfilling other eligibility requirements - Increase unduplicated number of participants - Limit number of participants served at any point in time - Suspend filling open waiver slots from waiting list except for reserve capacity priority groups - Temporarily modify processes for level of care evaluations or re-evaluations - Extend reassessment and reevaluation due dates - Permit virtual evaluations, assessments, and person-centered planning meetings in lieu of face-to-face 	<p>CMS sample Appendix K template for COVID-19; Emergency Preparedness and Response for HCBS 1915(c) Waivers index; State Waivers List.</p> <p>Per updated guidance in December 2020, CMS may extend emergency authorities adopted under Appendix K through up to six months after the PHE ends.</p>
		Covered Services	<ul style="list-style-type: none"> - Temporarily modify service scope or coverage - Temporarily exceed service limits or requirements for amount, duration, and prior authorization to address health and welfare issues presented by the emergency - Temporarily add services to address the emergency - Temporarily institute or expand opportunities for self-direction - Add home delivered meals - Add medical supplies, equipment and appliances Add assistive technology 	
		Service Planning & Delivery	<ul style="list-style-type: none"> - Temporarily modify person-centered plan development process and responsible individuals - Add electronic method of service delivery to continue services remotely in home - Adjust prior approval/authorization elements in approved waiver - Adjust assessment requirements - Add electronic method of document signing 	

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		Settings	<ul style="list-style-type: none"> - Temporarily expand settings where services may be provided - Temporarily provide services in out of state settings (if not already permitted in waiver) - Temporarily allow payment for services to support waiver participants in acute care hospital or short-term institutional stay, when necessary, supports are not available in that setting or when individual requires those services for communication and behavioral stabilization and services are not covered in such settings - Not allow visitors at any time to minimize spread of infection (for settings added after 3/17/14) 	
		Providers	<ul style="list-style-type: none"> - Temporarily permit payment for services rendered by family caregivers or legally responsible relatives (if not already permitted in waiver) - Temporarily modify provider qualifications - Temporarily increase payment rates - Temporarily include retainer payments to address emergency related issues - Extend emergency paid sick leave for personal care service providers unable to work due to COVID-19 - Allow case management entities to provide direct services 	
		Oversight	<ul style="list-style-type: none"> - Track COVID-19 cases among waiver enrollees - Otherwise temporarily modify incident reporting requirements, medication management, or other participant safeguards to ensure individual health and welfare and account for emergency circumstances - Extend time for submitting waiver enrollment and spending reports to CMS and/or suspend data collection for performance measures other than health and 	
		Cost Sharing	<ul style="list-style-type: none"> - Reduce or eliminate post-eligibility treatment-of-income contributions 	
Medicaid Redetermination Process	FFCRA/Administration	Redeterminations/Renewals	<p>FFCRA authorized a 6.2 percentage point FMAP increase for states that meet certain maintenance of eligibility (MOE) requirements. The additional funds were retroactively available to states beginning January 1, 2020 and continue through the quarter in which the PHE period ends.</p> <p>The CAA, 2023 set April 1, 2023 as the last date of the Medicaid continuous enrollment requirement as a condition of receiving enhanced FMAP. States may begin to process renewals starting on April 1, 2023. Additionally, the legislation phases out the 6.2 percentage point enhanced FMAP between April 1, 2023 and January 1, 2024.</p> <p>CMS has issued guidance advising states to initiate eligibility renewals for all individuals enrolled in Medicaid and CHIP within 12 months of the eventual end of the PHE, and to complete renewals within 14 months. The guidance emphasizes current rules requiring states to provide a smooth transition to other options for those who may no longer be eligible for Medicaid or CHIP once the PHE eventually ends.</p> <p>CMS will consider states to be in compliance with the 12-month unwinding period announced in the August 2021 SHO provided that the state has initiated all renewals and other outstanding eligibility actions by the last month of the 12-month period. States will have two additional months (14 months total) to complete all pending actions initiated during the 12-month unwinding period.</p>	<p>States may begin processing renewals on April 1, 2023.</p> <p>CMCS Informational Bulletin, January 2023</p>

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			<p>CMCS maintains a PHE unwinding landing page with resources, including a Communications Toolkit and updated strategies for partnering with managed care plans. CMS has continued to issue new guidance to states and other entities on the unwinding process. Additional guidance may be found here.</p> <p>The CAA, 2023 also establishes new reporting requirements. From April 1, 2023 through June 30, 2024, states must submit to CMS a monthly report detailing activities related to eligibility redeterminations.</p>	