

COVID-19 National Emergency & Public Health Emergency

Policy & Regulatory Updates:

Last Updated: 5/19/2023

COVID-19 Vaccines, Testing, Treatment

Update Name:	Date Released	Released By:	Summary:
<u>HHS Bridge Access Program For COVID-19 Vaccines and Treatments Program</u>	4/18/2023	Department of Health & Human Services	<p>Designed to create a \$1.1 billion public-private partnership to help maintain uninsured individuals' access to COVID-19 care at their local pharmacies, through existing public health infrastructure, and at their local health centers.</p> <p>The program has two major components:</p> <ol style="list-style-type: none"> 1. To provide support for the existing public sector vaccine safety net, which is implemented through local health departments and HRSA supported health centers. 2. Create a novel, funded partnership with pharmacy chains that will enable them to continue offering free COVID-19 vaccinations and treatments to the uninsured through their network or retail locations as has been done during the COVID-19 Public Health Emergency <p>This program is still being designed/implemented.</p> <ul style="list-style-type: none"> • Over the next few months, HHS will establish new contractual relationships with pharmacies, so that the program could be launched sometime in the Fall of 2023.

<p><u>CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency</u></p>	<p>2/27/2023</p>	<p>Centers for Medicare & Medicaid Services</p>	<p><u>Medicaid & CHIP:</u> states must provide coverage for vaccinations, testing, and treatments through the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE. The coverage requirement will end on September 30, 2024.</p> <p><u>Medicare:</u> People with Medicare coverage will continue to have access to COVID-19 vaccinations without cost sharing after the end of the PHE. Traditional Medicare can continue to receive COVID-19 PCR and antigen tests with no cost sharing. Medicare Advantage plans can continue to receive COVID-19 PCR and antigen tests when the test is covered by Medicare, but their cost-sharing may change when the PHE ends. No change in Medicare coverage of treatments for those exposed to COVID-19 once the PHE ends. In cases where cost sharing and deductibles apply now, they will continue to apply.</p> <p><u>Private Health Insurance:</u> People with private health insurance may need to pay part of the cost of an out-of-network provider vaccinating them (after PHE ends). Mandatory coverage for over the counter and laboratory-based COVID-19 PCR and antigen tests will end. If private insurance chooses to cover these items or services, there may be cost sharing, prior authorization, or other forms of medical management. Treatment coverage will not change. In cases where cost sharing and deductibles apply now, they will continue to apply.</p> <p><u>Uninsured:</u> Patients with temporary Medicaid coverage created through the State PHE flexibilities will lose COVID-19 testing services without cost sharing.</p>
<p><u>Maintenance of Effort (MOE) Requirement</u></p>	<p>3/18/2020</p>	<p>Families First Coronavirus Response Act (Legislation-116th Congress)</p>	<ul style="list-style-type: none"> • States could not change Medicaid benefits significantly throughout the PHE due to the Families First Coronavirus Response Act. <ul style="list-style-type: none"> ○ Expires at the end of the quarter in which PHE ends (June 30, 2024)

Telehealth Flexibilities

Update Name:	Date Released:	Released By:	Summary:
<u>Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications</u>	5/10/2023	Drug Enforcement Administration	<p>Telemedicine prescriptions</p> <ul style="list-style-type: none"> ○ Full COVID-19 telemedicine flexibilities, including prescribing controlled substance without an in-person visit, will remain in place until November 11, 2023. <p>Provider-patient relationship via telehealth</p> <ul style="list-style-type: none"> ○ If established on or before November 11, 2023, the same telemedicine flexibilities are permitted until November 11, 2024. <p><u>Temporary Final Rule</u></p> <ul style="list-style-type: none"> ○ Final rule timeline is unclear – hope to have it before November 2023
<u>CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency</u>	2/27/2023	Centers for Medicare & Medicaid Services	<p><u>Medicare:</u> Extended through December 31, 2024- People with Medicare can access telehealth services in any geographic area in the United States, rather than only those in rural areas. • People with Medicare can stay in their homes for telehealth visits that Medicare pays for rather than traveling to a healthcare facility. • Certain telehealth visits can be delivered audio-only (such as a telephone) if someone is unable to use both audio and video, such as a smartphone or computer.</p> <p><u>Medicaid & CHIP:</u> Coverage will vary by state. CMS encourages states to continue to cover Medicaid and CHIP services when they are delivered via telehealth.</p> <p><u>Private Health Insurance:</u> Coverage will vary by private insurance plan after the end of the PHE. When covered, private insurance may impose cost-sharing, prior authorization, or other forms of medical management on telehealth and other remote care services.</p>
<u>Medicare -</u>	6/6/2022	Centers for Medicare &	<ul style="list-style-type: none"> • Beginning January 1, 2022, FQHC mental health visits included visits

<p><u>Telehealth Behavioral Health Visits</u></p>		<p>Medicaid Services</p>	<p>furnished using interactive, real-time telecommunications technology.</p> <ul style="list-style-type: none"> ○ This change allowed FQHCs to report and receive payment for mental health visits furnished via real-time telecommunication technology in the same way they currently do when visits take place in-person, including audio-only visits. <ul style="list-style-type: none"> ● CMS finalized that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that in general: <ul style="list-style-type: none"> ○ There must be an in-person mental health service (without the use of telecommunications technology). ○ The service must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders. ● Exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient’s medical record). ● Section 4113 of the CAA, 2023 delayed the in-person requirements under Medicare for mental health services furnished through telehealth under the PFS and for mental health visits furnished by FQHCs via telecommunications technology. ● For FQHCs, in-person visits will not be required until January 1, 2025, if the PHE ends prior to that date.
<p><u>Medicare Physician Supervisor Requirements</u></p>	<p>5/10/2023</p>	<p>Centers for Medicare & Medicaid Services</p>	<p>Medicare Physician Supervision Requirement</p> <ul style="list-style-type: none"> ● CMS temporarily modified the regulatory definition of direct supervision, which required the supervising physician or practitioner to be “immediately available” to furnish assistance and direction during

			<p>the service, to include “virtual presence” of the supervising clinician using real time audio and video technology.</p> <ul style="list-style-type: none"> • This flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends.
<p><u>Prescribing of Controlled Substances When No In-Person Medical Evaluation Has Occurred</u></p>	<p>Proposed Rule 3/1/2023</p>	<p>Drug Enforcement Administration</p>	<p>Allows for the prescription of non-narcotic schedule III-V controlled medications when certain circumstances are met.</p> <ul style="list-style-type: none"> ○ Prior to issuing a prescription, review recent prescription drug monitoring program data, <i>i.e.</i>, data made available by the State in which the patient is located, regarding controlled medication prescriptions issued to the patient in the last year. <p>Initially limits prescriptions for a controlled medication issued to a patient to a 30-day supply (via telehealth prescription).</p> <ul style="list-style-type: none"> ○ Allowed to issue multiple prescriptions for the same patient but would only be allowed to prescribe an amount less than or equal to the total quantity of a 30-day supply. <p>Specifies the circumstances under which practitioners may prescribe controlled medications, to patients whom the practitioner has never evaluated in person, including:</p> <ul style="list-style-type: none"> ○ Such prescriptions are in accordance with applicable Federal and State laws. ○ Such practitioners possess an active DEA dispensing registration issued pursuant to the State in which the practitioner is located (unless exempted). <p>Requires practitioners to keep detailed records regarding prescriptions issued as a result of a telemedicine encounter at the registered location of their <u>21 CFR 1301.13(e)(1)(iv)</u> registration, in digital or paper form that is readily accessible.</p> <ul style="list-style-type: none"> ○ Prescribing practitioner must include a notation on the face of the prescription, or within the prescription order if prescribed

			electronically, that the prescription has been issued via a telemedicine encounter.
<u>Expansion of Induction of Buprenorphine via Telehealth Encounter</u>	Proposed Rule 3/1/2023	Drug Enforcement Administration	<p>Promulgates regulations that would expand the circumstances under which practitioners are authorized to prescribe any schedule III, IV, or V narcotic drug approved by the FDA specifically for use in the maintenance or detoxification treatment of OUD via a telemedicine encounter, including an audio-only telemedicine encounter.</p> <ul style="list-style-type: none"> ○ The only schedule III-V narcotic drug that is currently approved by the FDA for such treatment is buprenorphine. ○ DEA is proposing to expand the situations in which practitioners are authorized to prescribe buprenorphine via telemedicine for maintenance or detoxification treatment under limited circumstances. <p>Requires a practitioner to review and consider PDMP data prior to prescribing buprenorphine under the authority the regulations would grant.</p> <p>Requires the patient receiving to receive a medical evaluation meeting certain requirements within 30 days of being prescribed buprenorphine for the induction of OUD treatment to obtain an additional supply of buprenorphine.</p> <p>Requires practitioners to keep comprehensive records establishing the nature of the encounter, the patient's proffered reason for the audio-only encounter.</p>

**Amendment of Public Health & Readiness and Emergency Preparedness Act
for Medical Countermeasures Against COVID-19**

Update Name:	Date Released:	Released By:	Summary:
<u>Administering the COVID-19 Vaccine</u>	4/14/2023	Department of Health & Human Services	<p>Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.</p> <ul style="list-style-type: none"> ○ PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration. <p>Extending coverage through December 2024 for Federal agreements.</p> <ul style="list-style-type: none"> ○ This includes all activities related to the provision of COVID-19 countermeasures that are 1) provided based on a Federal agreement (including the vaccines and treatments purchased and provided by the USG), or 2) directly conducted by the USG, including by Federal employees, contractors or volunteers. <p>Ending of coverage for certain activities.</p> <ul style="list-style-type: none"> ○ Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities: <ul style="list-style-type: none"> ▪ COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students) ▪ COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns. <p>Ending of coverage for routine childhood vaccinations.</p> <ul style="list-style-type: none"> ○ Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.
<u>Administering the COVID-19 Vaccine</u>	2/16/2021	Department of Health & Human Services	<ul style="list-style-type: none"> • HHS amendment to the Public Readiness and Emergency Preparedness Act expanded who could order and administer the COVID-19 vaccine. • Dentists have been able to provide COVID-19 vaccines.

			<ul style="list-style-type: none"> Pharmacists have been able to provide COVID-19 vaccines. <ul style="list-style-type: none"> Other providers listed included: <ul style="list-style-type: none"> Midwives, paramedics, EMTs, physician assistants, respiratory therapists, podiatrists, optometrists, and veterinarians This amendment is scheduled to last until October 1, 2024, or until HHS declares a final day.
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Malpractice Coverage-Related Flexibilities:

Update Name:	Date Released:	Released By:	Summary:
<u>Determination of Coverage for COVID-19 Related Activities by Health Center Providers</u>	March 2020	Health Resources & Services Administration	<p>Health Centers were able to provide COVID-19-related services to non-established patients and were still covered for malpractice liability under the FTCA.</p> <p>No clear end date for this flexibility.</p> <ul style="list-style-type: none"> The provision of grant-supported health services by individuals who have been deemed as Public Health Service employees through the Health Center FTCA Program and the Health Center Volunteer Health Professional (VHP) FTCA Program, and who provide grant-supported health services to prevent, prepare or respond to COVID-19 to individuals who are established patients of the health center, whether at the health center or offsite, and whether in person or through telehealth, benefits patients of these entities and general populations that could be served by these entities through community-wide intervention efforts within the communities served by such entities, and therefore is eligible for liability protections for the provision of such services under section 42 U.S.C. § 233(g)-(n) and (q).

HIPPA

Update Name:	Date Released:	Released By:	Summary:
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<u>Enforcement Discretion for Telehealth Remote Communications</u>	3/17/2020	Department of Health & Human Services	<ul style="list-style-type: none"> Extended through the end of PHE (May 11, 2023)
<u>Disclosures by Business Associates</u>	4/2/2020	Department of Health & Human Services	<ul style="list-style-type: none"> Extended through the end of PHE (May 11, 2023)
<u>Enforcement Discretion at Community-Based Testing Sites</u>	3/12/2020	Department of Health & Human Services	<ul style="list-style-type: none"> Extended through the end of PHE (May 11, 2023)
<u>Online Scheduling for COVID Vaccines</u>	12/11/2020	Department of Health & Human Services	<ul style="list-style-type: none"> Extended through the end of PHE (May 11, 2023)

Workforce

Update Name:	Date Released:	Released By:	Summary:
<u>Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events</u>	10/6/2022	Health Resources & Services Administration	<ul style="list-style-type: none"> CMS has been waiving the requirements which require RHCs and FQHCs to be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS has temporarily waived this requirement, removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand service locations to meet the needs of Medicare beneficiaries. This flexibility includes areas that may be outside of the location requirements, for the duration of the PHE. CMS will end this waiver at the conclusion of the PHE.
<u>National Health Service Corps</u>	March 2020	Health Resources & Services Administration	Provided flexibilities relating to:

<u>COVID-19 Flexibility</u>			<ol style="list-style-type: none"> 1. Requirement of not being away from an approved service site for more than the allotted seven weeks per service year. 2. Unemployed as a direct result of the COVID-19 outbreak. 3. Employer-directed care outside of an NHSC-approved health care facility. <ul style="list-style-type: none"> • Flexibilities will end at the conclusion of the COVID-19 PHE (May 11, 2023)
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Medicaid Continuous Enrollment & Redeterminations

Update Name:	Date Released:	Released By:	Summary:
<u>End of the Medicaid Continuous Enrollment Condition Frequently Asked Questions for State Medicaid and CHIP Agencies May 12, 2023</u>	5/12/2023	Centers for Medicare & Medicaid Services	<p>Data Sharing State Medicaid or CHIP agencies may disclose beneficiary data to an enrolled provider so that the provider can assist in completing renewals without violating confidentiality standards.</p> <p>Resumption of Premiums States that implemented state disaster relief SPAs tied to the COVID-19 PHE must resume imposing Medicaid premiums consist with their state plans, unless they take action to delay or cancel the resumption of premiums.</p> <p>Premiums & Disenrollment Until January 1, 2024, states claiming the temporary FMAP increase may not increase Medicaid premium schedules over the amounts in place for each eligibility group subject to premiums as of January 1, 2020.</p> <p>States may disenroll beneficiaries who haven't paid Medicaid premiums for at least 60 days but with some limitations.</p> <p>Returned Mail Condition States need to conduct outreach through more than one modality under the returned mail condition if mail with a beneficiary's renewal notice or request for additional information is returned after an individual's coverage has been terminated.</p>
<u>Enhanced</u>	1/31/2023	Centers for Medicare &	<ul style="list-style-type: none"> • Separates the end of the FFCRA continuous enrollment condition from

<u>Federal Medicaid Assistance Percentage (FMAP) of 6.2%</u>		Medicaid Services	<p>the end of the COVID-19 public health emergency (COVID-19 PHE), and ends that condition on March 31, 2023, thus enabling states to terminate Medicaid enrollment of individuals who no longer meet Medicaid eligibility requirements on or after April 1, 2023.</p> <ul style="list-style-type: none"> • Amends the conditions states must meet to claim, and extends the availability of, the temporary FMAP increase beginning April 1, 2023, gradually phasing down the increase until December 31, 2023. • Adds new reporting requirements for all states under section 1902(tt) of the Social Security Act. • Creates new enforcement authorities for CMS related to the new reporting requirements and to state renewal activities during the period that begins on April 1, 2023, and ends on June 30, 2024.
<u>Key Dates Related to the Medicaid Continuous Enrollment Condition Provisions in the Consolidated Appropriations Act, 2023</u>	1/5/2023	Centers for Medicare & Medicaid Services	<p>Renewal Redistribution Plan:</p> <ul style="list-style-type: none"> • Submit By: February 1, 2023, for states initiating renewals in February and February 15, 2023, for all other states. <p>Systems Readiness Artifacts (Testing & Configuration Plans):</p> <ul style="list-style-type: none"> • Submit By: February 1, 2023, for states initiating renewals in February <ul style="list-style-type: none"> • February 15, 2023, for all other states. <p>Baseline Unwinding Data:</p> <ul style="list-style-type: none"> • Varies depending on when state begins renewals (February 8, 2023, March 8, 2023, or April 8, 2023).
General COVID-19 Updates			
Update Name:	Date Released:	Released By:	Summary:
<u>H.J. RES. 7 Relating to a national emergency</u>	Passed House: 1/9/2022, Passed Senate: 3/29/2023,	Legislation (118 th Congress)	<ul style="list-style-type: none"> • The Covid-19 national emergency declared by former President Donald Trump in March 2020 would be ended by H. J. Res. 7, which the Senate cleared for the president on March 29. <ul style="list-style-type: none"> ○ Trump issued the emergency declaration on March 13, 2020, in

declared by the President on March 13, 2020

Signed by President 4/10/2023

response to the outbreak of Covid-19. It followed the public health emergency that the Health and Human Services Department (HHS) first declared on Jan. 31, 2020.

- President Joe Biden extended the state of emergency several times and said earlier this year it would terminate on May 11, along with the public health emergency.
 - The national emergency declaration provided HHS emergency authority to temporarily waive or modify requirements under Medicare, Medicaid, and other health programs. The authority is intended to ensure sufficient health-care items and services are available during an emergency and provide protection to health-care providers if they can't meet certification or licensing requirements, for example.

What Did the National Emergency Do?

- Rolls back the enrollment and payment deadlines for individuals who have lost their jobs to sign up for COBRA or pay COBRA premiums.
- Reverses efforts to address prison crowding by terminating the CARES Act home confinement provisions and ending flexibilities allowing video court proceedings.
- Cuts preplanned sickness benefits and unemployment benefits for rail workers.
- Ends a number of other flexibilities affected by emergency management departments.
- Cancels the National Emergency Declaration would not end Title 42 at the border, which CDC based on the public health service act emergency.

Termination Process

- The National Emergencies Act places limits on the president's authority to declare a national emergency.
- The law allows the House and Senate to terminate a declared

			<p>emergency by passing a joint resolution using expedited procedures that prevent a Senate filibuster and require a simple majority for passage. The law also directs Congress to meet every six months to consider voting on such a measure, though the House and Senate haven't interpreted it as a requirement to vote, according to the Congressional Research Service.</p>
<p><u>Rescission of Requirements for Negative Pre-Departure COVID-19 Test Result (Traveling from China to the US)</u></p>	<p>3/14/2023</p>	<p>Centers for Disease Control & Prevention</p>	<ul style="list-style-type: none"> • Rescission of the Order requiring negative pre-departure COVID-19 test results or documentation of recovery from COVID-19 for aircraft passengers traveling to the United States from the People's Republic of China, including the Special Administrative Regions of Hong Kong and Macau. • This order was effective March 10, 2023.
<p><u>COVID-19 Origin Act 2023</u></p>	<p>Became Public Law: 3/20/2023</p>	<p>Legislation (118th Congress)</p>	<ul style="list-style-type: none"> • The administration would have to declassify information on potential links between China's Wuhan Institute of Virology and the origin of Covid-19 under S. 619. • The Office of the Director of National Intelligence would have to declassify information related to coronavirus research at the institute, researchers who fell ill in the fall of 2019, and activities performed at the institute with or on behalf of the Chinese military. • The agency would have to submit an unclassified report to Congress with all relevant information within 90 days of the bill's enactment. It could only redact information as needed to protect sources and methods.