

## Update on Covid-19 Health-Related Regulatory Waivers

### CURRENT STATUS

As of October 2022, some of New York State's Covid-19 health care-related regulatory waivers are beginning to expire. To date, Governor Hochul has issued three Executive Orders related to health care regulatory flexibilities:

- Executive Order 4, issued on September 27, 2021, is intended to address the health care workforce shortage. The Order and its subsequent modifications reinstated a number of the emergency provisions that had originally lapsed with the end of New York's original Covid-19 public health emergency that expired on June 24, 2021. The order has been extended as of September 27, 2022, and will now expire October 27, 2022 unless further extended.
- Executive Order 6, issued on October 8, 2021, revoked all other Executive Orders issued by previous governors, except for those listed in the Order, including all of former Governor Cuomo's Covid-19-related orders that had not already expired.
- Executive Order 11, issued on November 26, 2021, declared a disaster emergency in New York State due to the spread of the Omicron variant and implementing the State's Comprehensive Emergency Management Plan due to increased Covid-19 transmission rates and hospital admissions. Executive Order 11 expired on September 13, 2022.

Other flexibilities are in the process of being, or have already been, made permanent. These particularly include those relating to the expansion of telehealth as a service delivery modality.

This document is an update of SPG's Regulatory Waiver Tracker to show which flexibilities are still in effect, which have expired (in **red**), and which have been made permanent (in **green**) as of October 2022. This document also includes a summary of NYS agency policy and relevant federal guidance, starting on page 7.

SPG will continue to update this document as further changes occur.

**Current New York State Waivers**

<b>Waiver</b>	<b>Effective Date</b>	<b>Waiver Type</b>	<b>Permissions</b>	<b>Expiration</b>
<b>DFS <a href="#">62<sup>nd</sup> Amendment to Insurance Regulation 62</a></b>	June 4, 2021	Telehealth Flexibilities	<ul style="list-style-type: none"> <li>Clarifies that the definition of telehealth includes audio-only visits.</li> <li>Clarifies that an insurer may engage in reasonable fraud, waste, and abuse detection efforts, including to prevent payments for services that do not warrant a separate billable encounter.</li> </ul>	<b>Made permanent</b> on December 22, 2021 in the <a href="#">State Register</a> .
<b>DFS <a href="#">57<sup>th</sup> Amendment to Insurance Regulation 62</a></b>	March 6, 2020	Cost Sharing	<ul style="list-style-type: none"> <li>Requires plans to waive cost-sharing for COVID-19 testing.</li> </ul>	<a href="#">Extended</a> to December 7, 2022.
<b>DFS <a href="#">Circular Letter No. 9</a> and <a href="#">Supplements No. 1, No. 2, No. 3, No. 4</a></b>	March 25, 2020	Insurance Producer Flexibilities	<ul style="list-style-type: none"> <li><i>Suspends the expiration of licenses for insurance producers.</i></li> </ul>	<b>EXPIRED</b> as of September 6, 2020.
			<ul style="list-style-type: none"> <li>Suspends the requirement that a monitor be present to complete producer continuing education and pre-licensing course exams.</li> </ul>	<b>Made permanent</b> by Supplement <a href="#">No. 4</a> .

**Current New York State Waivers**

Waiver	Effective Date	Waiver Type	Permissions	Expiration
<b>DOH Emergency Regulations</b>	July 30, 2021 (August 12, 2021 for Covid-19 Confirmatory testing)	Vaccine and Testing Requirements	<ul style="list-style-type: none"> <li>• <u>Covid-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel</u> (<a href="#">here</a>)                             <ul style="list-style-type: none"> <li>○ Requires adult care facilities (within 7 days) and nursing homes (within 14 days) to offer unvaccinated personnel and residents an opportunity to receive a first or second dose of the Covid-19 vaccine.</li> <li>○ <b>Note: DOH has removed the requirement for nursing homes and adult care facilities to certify on a weekly basis that the facility has complied with the regulation.</b></li> <li>○ <b>Made permanent</b> at the September 15<sup>th</sup> PHHPC meeting with minor changes.</li> </ul> </li> <li>• <u>Hospital and Nursing Home Personal Protective Equipment (PPE) Supply</u> (<a href="#">here</a>):                             <ul style="list-style-type: none"> <li>○ Requires hospitals and nursing homes to have a 60-day supply of PPE by August 31, 2021 (hospitals were previously required to have a 90-day stockpile) and authorizes the Commissioner of Health to increase the requirements to 90 days for hospitals during a state or local public health emergency.</li> </ul> </li> <li>• <u>Surge and Flex Health Coordination System</u> (<a href="#">here</a>):                             <ul style="list-style-type: none"> <li>○ Establishes ongoing emergency planning requirements (“Surge and Flex Health Care Coordination System”) for facilities and agencies regulated by DOH and authorizes the Commissioner of Health to direct health care facilities to increase bed capacity by 50 percent (previously up to 100% within 30 days of emergency declaration) and to postpone all non-essential elective procedures.</li> </ul> </li> </ul>	<p><a href="#">Extended</a> by the Public Health and Health Planning Council (PHHPC) at the September 15<sup>th</sup> PHHPC meeting.</p> <p>Proposed to be made permanent and currently under review, unless otherwise noted.</p>
			<ul style="list-style-type: none"> <li>• <u>Covid-19 Confirmatory Testing</u> (<a href="#">here</a>):                             <ul style="list-style-type: none"> <li>○ Requires hospitals and nursing homes to test patients and residents for Covid-19 if they are presenting symptoms or if they have been exposed to Covid-19.</li> <li>○ Requires hospitals and nursing homes to test deceased patients and residents for Covid-19 within 48 hours after death if there is a clinical suspicion that Covid-19 was the cause of death and if no such test was performed in the 14 days prior to death.</li> <li>○ Requires funeral directors, coroners, and medical examiners to administer tests for Covid-19 within 48 hours after death if there is a reasonable suspicion that Covid-19 was the cause of death and if no such test was performed in the 14 days prior to death.</li> </ul> </li> </ul>	<p><b>EXPIRED</b> as of November 9, 2021.</p>

<p><b>NYS Executive Order 4</b></p>	<p>September 27, 2021</p>	<p>Provider Flexibilities</p>	<p>The Order reinstates many workforce and scope of practice flexibilities that applied during the original New York State Covid-19 public health emergency. Specifically, it temporarily suspends or modifies specific regulations that include the following:</p> <p><u>Licensure and Registration</u></p> <ul style="list-style-type: none"> <li>• Allows certain providers who are licensed in other states or in Canada or other approved countries, or who are licensed but not registered in NYS, to practice in NYS, including: <ul style="list-style-type: none"> <li>○ Physicians and physician assistants;</li> <li>○ Registered nurses, licensed practical nurses, and nurse practitioners;</li> <li>○ Clinical nurse specialists, specialist assistants, and similar titles;</li> <li>○ Radiologic technicians;</li> <li>○ Respiratory therapists and respiratory therapy technicians;</li> <li>○ Midwives; and</li> <li>○ Licensed master social workers and licensed clinical social workers.</li> </ul> </li> <li>• Allows recent graduates of certain health care programs to practice in NYS under supervision.</li> <li>• Waives re-registration fees, creating an expedited re-registration process, and eliminates barriers to re-enter the workforce for retirees.</li> </ul> <p><u>Scope of Practice</u></p> <ul style="list-style-type: none"> <li>• Allows physician visits for nursing home residents to be conducted via telemedicine.</li> <li>• Allows hospitals to use qualified volunteers or personnel affiliated with different hospitals.</li> <li>• Permits additional personnel (e.g., EMT-paramedics, midwives) to administer Covid-19 and influenza vaccines.</li> <li>• Allows physicians and practitioners to use non-patient specific regimens to facilitate Covid-19 testing and vaccination.</li> <li>• Permits a nurse practitioner to provide medical services appropriate to their education, training, and experience, without a written practice agreement or collaborative relationship with a physician. <b>EXPIRED per EO 4.8</b></li> <li>• Provides flexibility to emergency medical services personnel, including: <ul style="list-style-type: none"> <li>○ Allowing the use of community paramedicine, alternative destinations, treatment in place through telemedicine, and other services as approved by the Commissioner of Health, and</li> <li>○ Allowing EMTs to provide other emergent and non-emergent services beyond settings currently authorized, such as hospitals.</li> </ul> </li> </ul> <p><u>Prior Authorization:</u> <b>EXPIRED per EO 4.12</b></p> <ul style="list-style-type: none"> <li>• Suspends requirements for preauthorization review for scheduled surgeries.</li> <li>• Suspends concurrent review for inpatient and outpatient hospital services.</li> <li>• Suspends retrospective review for inpatient/outpatient hospital services at in-network hospitals.</li> <li>• Tolls statutory timeframes for hospitals to submit internal and external appeals.</li> </ul> <p><u>Other</u></p> <ul style="list-style-type: none"> <li>• Allows hospitals and nursing homes to safely discharge, transfer, or receive patients as necessary due to staffing shortages.</li> <li>• Provides flexibilities for clinical labs to increase testing capacity, including by employing recent graduates.</li> </ul> <p>Executive Order 4.1 adds the following modifications:</p>	<p><u>Extended</u> by Executive Order 4.13 through October 27, 2022, unless otherwise noted.</p>
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**Current New York State Waivers**

Waiver	Effective Date	Waiver Type	Permissions	Expiration
<b>EO 4 (continued)</b>		Provider Flexibilities	<ul style="list-style-type: none"> <li>• Expands the authorization for individuals who were temporarily authorized to perform Covid-19 testing to perform any clinical laboratory test, under appropriate supervision.</li> <li>• Permits initial patient visits for home health to be made within 48 hours of acceptance of a community referral or return home from institutional placement.</li> <li>• Permits home health agencies to conduct in-home supervision “as soon as practicable” or by telephone or video.</li> <li>• Adds further flexibilities related to testing.</li> </ul> <p>Executive Orders 4.3 and 4.4:</p> <ul style="list-style-type: none"> <li>• Permit health care facilities to continue to employ surgical technologists who failed to meet the minimum standards within two years of the start of employment or contracting for the performance of surgical technology.</li> <li>• Indicate that failure of a nursing home to meet the daily average staffing hours will not be held in violation of the Public Health Law. <b>EXPIRED per EO 4.7</b></li> <li>• Indicate that failure or a residential health care facility to spend a minimum of 70 percent of revenue on direct resident care, and 40 percent of revenue on resident-facing staffing, will not be held to be a violation of the Public Health Law. <b>EXPIRED per EO 4.7</b></li> </ul>	<b>Extended</b> by Executive Order 4.13 through October 27, 2022, unless otherwise noted.
<b>NYS Executive Order <a href="#">11</a></b>	November 26, 2021	Emergency/ Capacity Management	<ul style="list-style-type: none"> <li>• Implements the State’s Comprehensive Emergency Management Plan and the “Surge and Flex” system, which allows DOH to limit non-essential elective procedure at health systems with limited capacity (defined as having below 10% staffed bed capacity available, or as otherwise determined by DOH).</li> <li>• Allows laboratories holding a CLIA certificate and meeting the CLIA quality standards to perform Covid-19 testing.</li> </ul>	<b>EXPIRED</b> as of September 13, 2022.

**Expired New York State Waivers**

<b>Waiver</b>	<b>Effective Date</b>	<b>Waiver Type</b>	<b>Permissions</b>	<b>Expiration</b>
<b>DFS 58<sup>th</sup> Amendment to Insurance Regulation 62</b>	3/16/2020	Cost Sharing	Requires plans to waive cost-sharing for services delivered via telehealth.	<b>EXPIRED</b> on June 4, 2021.
<b>DFS <a href="#">Circular Letter No. 8</a> and <a href="#">Supplements No. 1, No. 2</a></b>	3/20/2020 4/22/2020 6/26/2020	Provider Flexibilities	<i>Suspends various utilization review requirements and requires expedited payment of hospital claims. <b>EXPIRED</b> June 18, 2020; however, certain preauthorization requirements were temporarily reinstated per Circular Letter No. 17 (see below).</i>	<b>EXPIRED</b> June 18, 2020.
<b>DFS <a href="#">Circular Letter No. 10</a> and DFS <a href="#">60<sup>th</sup> Amendment to Insurance Regulation 62</a></b>	5/2/2020	Cost Sharing	Requires regulated health insurance plans to waive out-of-pocket costs (i.e. cost-sharing, deductibles, copayments, and coinsurance) for in-network mental health services for frontline essential workers during the COVID-19 emergency.	<b>EXPIRED</b> on May 26, 2021.
<b>DFS <a href="#">Circular Letter No. 17</a></b>	12/23/20	Provider Flexibilities	<p><i>Directs insurers to suspend the following requirements:</i></p> <ul style="list-style-type: none"> <li>• <i>Preauthorization review for urgent or non-elective scheduled inpatient surgeries, hospital admissions, and transfers between hospitals;</i></li> <li>• <i>Preauthorization review for inpatient rehabilitation and home health care services following an inpatient hospital admission;</i></li> <li>• <i>Preauthorization review for inpatient mental health services following an inpatient hospital admission; and</i></li> <li>• <i>Notification requirements that include the submission of medical records by the hospital to the insurance plan following an emergency hospital admission or financial penalties on a hospital for failure to provide notification of an emergency admission.</i></li> </ul>	<b>EXPIRED</b> February 21, 2021.

## NEW YORK STATE POLICIES

### Department of Health (DOH)

DOH issued emergency telehealth regulations (available [here](#)) to allow Medicaid providers to continue to provide telehealth services, including audio-only telephone services, following the conclusion of the State Covid-19 Disaster Emergency. DOH released updated guidance (available [here](#)), indicating that Medicaid providers will be permitted to continue providing services under the same flexibilities awarded by DOH during the State Disaster Emergency until permanent regulations are promulgated. The guidance largely does not include significant changes but does clarify that Article 29-I health facilities serving children in foster care are eligible to provide services via telehealth.

#### Proposed Telehealth Regulations

On March 23<sup>rd</sup>, DOH published proposed permanent regulations in the State Register (available [here](#)) that would add a new Part 538 to Title 18 of the New York Codes, Rules, and Regulations (NYCRR), outlining state reimbursement for telehealth services. The proposed regulation:

- Expands the types of providers who can deliver care via telehealth, as long as such telehealth services are appropriate to meet a patient's needs and are within a provider's scope of practice; and
- Adds audio-only, eConsult, virtual check-in, and virtual patient education as telehealth modalities, as well as parameters for appropriately using these modalities and standards for reimbursement.

The proposed regulations are available [here](#). DOH has adopted these rules on an emergency basis and renewed them several times, most recently in the August 31<sup>st</sup> State Register. They are currently **scheduled to expire November 13<sup>th</sup>**.

#### Other Guidance

For Health Homes serving adults and children, Care Management Agencies (CMAs), and Care Coordination Organizations/Health Homes (CCOs) serving individuals with intellectual and developmental disabilities, DOH has indicated that flexibilities granted to such entities will continue for the duration of the federal PHE, or until notified by DOH, whichever comes first. However, DOH implores Health Homes, CMAs, and CCOs to work towards full reinstatement of non-emergency policy, procedures, and timelines in anticipation of the end of Covid-19 flexibilities. DOH anticipates that providers will have at least 30 days' notice prior to the termination of flexibilities. Such flexibilities that **remain in place** include:

- Use of electronic signatures, which will continue to be an acceptable Health Home practice permanently.
- Verbal consent when all other methods of obtaining consent are exhausted, permitted that a wet or electronic signature is obtained within 60 days of verbal consent.
- Extended timeframe for completion of the comprehensive assessment and plan of care for new members to 120 days from 60 days.
- Waiver of face-to-face requirements.

DOH also released the following updated guidance documents for Health Homes, children's providers vaccine providers, laboratories, and other providers:

- [Updated Nursing Home Testing Requirements](#)

- [Rescission of Updated COVID-19 Guidance for the Authorization of Community Based Long Term Services and Supports Covered by Medicaid](#)
- [Revised Skilled Nursing Facility Visitation](#)
- [Updated Adult Care Facility Visitation, Communal Dining and Activities and Construction Projects](#)
- [Medicaid Pharmacy Guidance Regarding the End of the Declared Disaster Emergency in the State of New York - COVID-19](#)
- [Expiration of Medicaid Pharmacy Guidance Regarding the Declared Disaster Emergency in the State of New York - COVID-19](#)
- [Notification to Hospital CEOs and Nursing Home Administrators Regarding COVID-19 Discharge Testing](#)
- [Expiration of Suspended Health Plan Utilization Review Requirements](#)
- [DOH Notice to All Laboratories Supporting SAR-CoV-2 Testing](#)
- [DOH Notice to Clinical Laboratories with Temporary Approval](#)
- [DOH Notice to Clinical Laboratories Regarding Remote Supervision](#)
- [DOH Notice to Clinical Laboratories Operating as Patient Service Centers](#)
- [NYSIIS/CIR Reporting Requirements for the COVID-19 Vaccination Program](#)
- [COVID-19 Guidance for Health Homes](#)
- [COVID-19 Guidance Regarding 1915\(c\) HCBS Children’s Waiver](#)
- [COVID-19 Guidance for CFTSS Providers](#)
- [Guidance for 1915\(c\) HCBS Children’s Waiver Respite Providers](#)

## Office of Mental Health (OMH)

Following the end of the State Disaster Emergency, OMH released a regulatory waiver (available [here](#)) and a corresponding amendment (available [here](#)) that grants temporary relief from various requirements of Title 14 of NYCRR, in recognition of the ongoing effects of Covid-19 on operations. The waived provisions that **will continue** include:

- Regulations around the provision of telehealth services, including temporary approvals, expanded practitioner types, and audio-only services.
- Requirements continuing the reduction of minimum service durations and allowing rounding up of service times.
- Requirements to waive timeframes around treatment planning reviews and to waive initial in-person assessments.

OMH has extended the waiver several times, most recently [extending](#) the waiver **through October 4<sup>th</sup>**.

## Finalized Regulations

OMH finalized new regulations on telehealth in the September 28, 2022 State Register [here](#). The regulations revise Part 596 of Title 14 of NYCRR that regulates the provision of services via telehealth. The regulations:

- Allow for the provision of telephonic (audio-only) services;
- Allow any authorized provider to deliver mental health services under their scope of practice;
- Expand the definitions of originating and distant sites;



- Remove the required in-person initial assessment;
- Remove additional requirements for Personalized Recovery Oriented Services (PROS) and Assertive Community Treatment (ACT) programs; and
- Strengthen language around consent and recipient preference.

The text of the regulations is available [here](#). SPG’s summary of the regulations is available [here](#). OMH is also finalizing edits to a telehealth guidance document expected to be released shortly.

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## Other Guidance

On October 31, 2021, OMH released supplemental disaster emergency billing and documentation guidance (available [here](#)) for the following programs:

- Assertive Community Treatment (ACT)
- Personalized Recovery Oriented Services (PROS)
- Continuing Day Treatment (CDT)
- Children’s Day Treatment
- Partial Hospitalization Programs (PHP)
- Adult Behavioral Health HCBS
- Adult and Children’s Residential Programs
- Clinics

OMH will continue to allow flexibilities for billing and documentation as outlined in OMH-issued Covid-19 guidance (available [here](#)) for the duration of the federal PHE for these programs. When the federal PHE expires, providers will be immediately required to resume appropriate billing and documentation activities pursuant to pre-pandemic guidance and regulations.

On March 4, 2022, OMH released a revised Covid-19 infection control manual (available [here](#)).

## Office of Addiction Services and Supports (OASAS)

On June 25, 2021, OASAS issued a regulatory waiver (available [here](#)) continuing Covid-19 disaster emergency-related flexibilities for OASAS programs. The waiver was extended several times and was allowed to lapse in July 2022. OASAS published a chart of flexibilities and expiration dates [here](#) (last updated April 20, 2022).

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## Final Regulations

On November 24, 2021, OASAS issued an emergency/proposed rule in the State Register (available [here](#)) amending Part 830 of Title 14 of NYCRR to continue telehealth flexibilities allowed during the New York State Disaster Emergency and to make those flexibilities permanent in alignment with the proposed regulations released by OMH. The rule, which was adopted on February 16<sup>th</sup>, also adds an optional LGBTQ endorsement to

develop a distinction for OASAS-certified programs meeting additional criteria for the provision of LGBTQ-affirming care. The final regulations are available [here](#). OASAS is in the process of finalizing changes to its telehealth guidance.

The following telehealth flexibilities have been **made permanent** through adopted amendments to 14 NYCRR Part 830:

- Allow for the telehealth practitioner’s distant site to be located anywhere within the United States.
- Allow for the patient’s originating site to include temporary locations out-of-state.
- Allow for telephonic-only services.
- Allow for all OASAS services to be provided via telehealth if appropriate.
- Define telehealth practitioner as any staff credentialed or approved by OASAS providing services consistent with their scope of practice.
- Waive requirement that patients have an initial in-person evaluation prior to receiving telehealth services.

The following provider flexibilities **will continue for the duration of the federal PHE**:

- Allow DATA 2000 waived practitioners to provide buprenorphine induction via telehealth and telephone-only.
- Allow providers to utilize certain video-conference technologies that are not fully compliant with HIPAA rules.
- Allow providers to use verbal consent to provide services, as documented in the patient record, until written consent can be obtained (written consent is still required to share patient records).

As of June 25, 2021, flexibilities regarding background checks have **ended**:

- OASAS providers must resume routine processing of background checks for all prospective employees, including for staff hired on or after June 24, 2021.
- In cases where background checks were abbreviated, required background checks must be submitted by August 25, 2021.
- Staff members with abbreviated background checks and who have regular and substantial contact with patients must be supervised in accordance with OASAS regulations, beginning September 25, 2021.

The following flexibilities expired with the Commissioner’s waiver in July 2022:

- Waive requirements for application and operating certificate designation for certified program approval to deliver telehealth services.
- Waive APG requirements regarding minimum time requirements for service delivery.

In addition, out-of-state practitioners that are not licensed in New York State are no longer permitted to deliver services.

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## **Other Guidance**

OASAS has released the following guidance documents for providers:

- [Return to Work Guidance](#)
- [Notification and Attestation Checklist for Staff Return to Work During Quarantine](#)
- [OASAS Guidance on Covid-19 Mask Wearing Requirements in Certified, Funded or Otherwise Authorized Settings](#)
- [Opioid Treatment Program Reopening Guidance](#)
- [Covid-19 Guidance for Outpatient Programs](#)

- [Interim Inpatient and Residential Program Guidance](#)
- [Reopening Guidance for Prevention Services Programs](#)
- [OASAS Reopening Guidance](#)

## Office for People with Developmental Disabilities (OPWDD)

OPWDD released guidance on July 2, 2021 (available [here](#), updated September 15, 2021) notifying providers to:

- Operate programs at full capacity to the extent possible;
- Resume unrestricted visitation at community outings from residential facilities; and
- Remove capacity limitations during transportation if all individuals are vaccinated.

Providers should immediately resume the pre-pandemic criminal background check process and all mandatory training requirements. All agencies and operating facilities must require all staff, volunteers, contractors, vendors, visitors, and individuals to wear appropriate face coverings unless exempt due to age, risk, or disability.

OPWDD's Amendment 06 to its 1915(c) waiver, which was approved by CMS and is effective July 1<sup>st</sup>, includes changes to permanently adopt telehealth and in-residence service delivery models initially used to address Covid-19. Other flexibilities provided in Appendix K may be continued up to **six months after the end of the ongoing federal PHE**.

OPWDD has released the following updated guidance documents regarding the expiration of flexibilities:

- [OPWDD's Emergency Regulation 14 NYCRR Section 633.26 Mandatory Face Coverings in OPWDD Certified Services and Facilities](#)
- [Notification and Attestation Checklist for Staff Return to Work During Quarantine](#)
- [Care Planning and Service Options Post Pandemic](#)
- [Interim Guidance Regarding the Use of Telehealth/COVID-19](#)
- [Expiration of Interim Guidance Regarding the Criminal Background Check Process for Staff Members](#)
- [Updated Interim Training & Recertification Guidance](#)

On October 27, 2021, OPWDD posted a public notice in the State Register (available [here](#)) announcing that, effective November 1, 2021, it will allow reimbursement for the remote delivery of Crisis Services for Individuals with Intellectual and/or Developmental Disabilities (CSIDD). Remote delivery may include telephonic (audio-only) technology in accordance with New York State and federal regulations.

## State Education Department (NYSED)

NYSED has published an Advisory Notice (available [here](#)) stating that licensure and scope of practice exemptions pursuant to Executive Order 202 have expired and Title VIII professionals should return to compliance with all statutory and regulatory requirements without delay, unless specifically suspended or waived pursuant to Executive Order 4. However, the federal PREP Act remains in effect and continues to provide certain authorizations and exemptions for many professions and activities related to the ongoing Covid-19 emergency response.

## FEDERAL POLICIES

### HHS PREP Act Declaration

HHS issued a Declaration under the PREP Act in March 2020 to expand flexibility and waive liability for health care providers to offer “covered countermeasures” for Covid-19. Such countermeasures include any drug, biological product, or device used to address the pandemic, as authorized for use by the Food and Drug Administration. A January 28, 2021 amendment to this Declaration (available [here](#)) explicitly authorized additional personnel to prescribe, dispense, and administer Covid-19 vaccinations and other “covered countermeasures” for Covid-19. The amendment:

- Authorizes any health care provider licensed in a state to administer Covid-19 vaccinations in any other state or territory;
- Authorizes any physician, registered nurse, or practical nurse whose license or certification expired within the past five years to administer Covid-19 vaccinations, as long as the license was in good standing at the time of expiration; and
- Requires such personnel to complete Covid-19 vaccination training and, if their license is expired, complete an on-site observation period under a currently practicing professional.

The PREP Act Declaration preempts any state law that would otherwise prohibit healthcare professionals who are “qualified persons” from prescribing, dispensing, or administering Covid-19 vaccines or other covered countermeasures. As such:

- State-licensed pharmacists may order and administer, and licensed or registered pharmacy interns may administer under supervision, FDA authorized, licensed, or approved Covid-19 vaccines following immunization training.
- State-licensed pharmacists may order and administer Covid-19 tests, including serology tests.
- Healthcare personnel using telehealth to order or administer covered countermeasures for patients in a state other than the state where the healthcare personnel are licensed or permitted to practice.

## Medicare

### Current Status of Telehealth Waivers

Since the federal PHE remains in place, Medicare’s Covid-19 telehealth policies and flexibilities remain in effect, including the ability to deliver services via telehealth to Medicare beneficiaries regardless of geographic restrictions or distant/originating site limitations and to deliver certain services via audio-only telephonic modalities. In December 2020, CMS [added](#) a large number of services to the telehealth permissible list, some on a permanent basis, some temporarily for the emergency, and some that will be available until the end of the calendar year in which the PHE ends.

CMS finalized its proposal to maintain much of the Medicare telehealth expansion that occurred during the Covid-19 public health emergency for two years, through December 31, 2023. This includes allowing all services defined by CPT code that have been temporarily added to the Medicare telehealth list (on a “Category 3” basis) to continue through that date, allowing CMS to gather more information to consider adding them permanently. A complete list of allowable telehealth services is available [here](#).

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## Medicare Telehealth After the End of the PHE: Mental Health

CMS finalized implementation of provisions in the Consolidated Appropriations Act, 2021 to permanently expand telehealth, with restrictions, for certain mental health services. CMS finalized removal of Medicare geographic restrictions on telehealth for mental health providers who have an existing and ongoing in-person relationship with a patient. This requires an in-person, non-telehealth service to be conducted by the provider within six months prior to the initial telehealth service, and every 12 months thereafter. The in-person follow-up exam requirement may be waived based on the provider's professional judgment that the patient may be at risk for disengagement with care, that the service would be likely to disrupt service delivery, or that it might create risks and burdens for the patient. Practitioners must document the exception and the patient's ability to obtain point-of-care testing during each 12-month interval.

CMS has also clarified that mental health services include services for treatment of substance use disorders (SUD). Additionally, CMS finalized a revised definition of "interactive telecommunications system" to include audio-only communication technology when used for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients in their homes. However, the use of audio-only is limited to providers who can provide two-way audio and video communications but use audio-only communications due to beneficiary choice.

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## Medicare Telehealth After the End of the PHE: Temporary Extension

In March 2022, Congress passed and President Biden signed an omnibus spending package that includes an extension of pandemic-related telehealth services in Medicare. The bill extends, for 151 days following the end of the Covid-19 PHE, the expansion of Medicare coverage of telehealth services that has been in place during the PHE. During this period:

- The lifting of the rural geographic restriction on Medicare telehealth will remain in effect.
- Medicare will continue to reimburse FQHCs and rural health clinics will for services provided through telehealth.
- Medicare will continue to pay for audio-only telehealth and physical, occupational, and speech therapy services delivered through telehealth.
- Medicare will continue not to enforce the requirement that beneficiaries receiving telehealth for mental health services must be seen in person by their provider within six months of starting treatment, and every year thereafter.
- Prescription of controlled substances will not be allowed via telehealth.

The omnibus bill text is available [here](#) and a summary is available [here](#).