

60 East 42nd Street, Suite 1762 New York, NY 10165 Phone: 212 827 0660 Fax: 212 827 0667

Update on Covid-19 Health-Related Regulatory Waivers and Requirements

CURRENT STATUS

As of February 2023, some of New York State's Covid-19 health care-related regulatory waivers are beginning to expire, and the federal Covid-19 Public Health Emergency (PHE) will expire on May 11, 2023.

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 February 21, 2023 and will now expire March 23, 2023 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 February 2023. This document also includes a summary of current vaccine/mask mandates (page 7) and NYS agency policy and relevant federal guidance (page 10).

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

Current New York State Waivers				
Waiver	Effective Date	Waiver Type	Permissions	Expiration
DFS 62nd Amendment to Insurance Regulation 62	June 4, 2021	Telehealth Flexibilities	 Clarifies that the definition of telehealth includes audio-only visits. 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. 	Made permanent on December 22, 2021 in the State Register.
DFS 57 th Amendment to Insurance Regulation 62	March 6, 2020	Cost Sharing	Requires plans to waive cost-sharing for COVID-19 testing.	Extended to March 6, 2023.
DFS <u>Circular</u> <u>Letter No. 9</u> and Supplements <u>No. 1, No. 2,</u>	March 25, 2020	Insurance Producer Flexibilities	Suspends the expiration of licenses for insurance producers.	EXPIRED as of September 6, 2020.
No. 3, No. 4			• Suspends the requirement that a monitor be present to complete producer continuing education and pre-licensing course exams.	Made permanent by Supplement No. 4.

Current New York State Waivers						
Waiver	Effective Date	Waiver Type	Permissions	Expiration		
DOH Emergency Regulations	July 30, 2021 (August 12, 2021 for Covid-19 Confirmatory testing)	Vaccine and Testing Requirements	 Covid-19 Vaccinations of Nursing Home and Adult Care Facility Residents and Personnel: 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. 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. Made permanent effective September 28, 2022 (final regulations here). Hospital and Nursing Home Personal Protective Equipment (PPE) Supply (here): 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. Surge and Flex Health Coordination System: 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. Made permanent effective December 28, 2022 (final regulations here). 	Extended through April 25, 2023 (hospital/nursing home PPE supply), unless otherwise noted.		
			 Covid-19 Confirmatory Testing (here): 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. 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. 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. 	EXPIRED as of November 9, 2021.		

NYS Executive Order 4	September 27, 2021	Provider Flexibilities	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: Licensure and Registration 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: Physicians and physician assistants; Registered nurses, licensed practical nurses, and nurse practitioners; Clinical nurse specialists, specialist assistants, and similar titles; Registered nurses, licensed practical nurses, and nurse practitioners; Respiratory therapists and respiratory therapy technicians; Respiratory therapists and respiratory therapy technicians; Allowives; and Licensed master social workers and licensed clinical social workers. Allows recent graduates of certain health care programs to practice in NYS under supervision. EXPIRED per EO 4.18 Waives re-registration fees, creating an expedited re-registration process, and eliminates barriers to re-enter the workforce for retirees. Scope of Practice Allows physician visits for nursing home residents to be conducted via telemedicine. Allows hospitals to use qualified volunteers or personnel affiliated with different hospitals. EXPIRED per EO 4.18 Permits additional personnel (e.g., EMT-paramedics, midwives) to administer Covid-19 and influenza vaccines. Allows physicians and practitioners to use non-patient specific regimens to facilitate Covid-19 testing and vaccination. Provides flexibility to emergency medical services personnel, including: Allowing the use of community paramedicine, alternative destinations, treatment in place through telemedicine, and other services as approved by the Commissioner of Health, and Allowing EMTs to provide other emergent and non-emergent services beyond settings currently authorized, such as hospitals. Prior Authorization: EXPIRED per EO 4	Extended by Executive Order 4.18 through March 23, 2023 unless otherwise noted.
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Current New York State Waivers					
Waiver	Effective Date	Waiver Type	Permissions	Expiration	
EO 4 (continued)		Provider Flexibilities	 Expands the authorization for individuals who were temporarily authorized to perform Covid-19 testing to perform any clinical laboratory test, under appropriate supervision. 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. Permits home health agencies to conduct in-home supervision "as soon as practicable" or by telephone or video. Adds further flexibilities related to testing. Executive Orders 4.3 and 4.4: 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. 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. EXPIRED per EO 4.7 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. EXPIRED per EO 4.7 	Extended by Executive Order 4.17 through February 21, 2023 unless otherwise noted.	
NYS Executive Order 11	November 26, 2021	Emergency/ Capacity Management	 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). Allows laboratories holding a CLIA certificate and meeting the CLIA quality standards to perform Covid-19 testing. 	EXPIRED as of September 13, 2022.	

	Expired New York State Waivers				
Waiver	Effective Date	Waiver Type	Permissions	Expiration	
DFS 58 th Amendment to Insurance Regulation 62	3/16/2020	Cost Sharing	Requires plans to waive cost-sharing for services delivered via telehealth.	EXPIRED on June 4, 2021.	
DFS <u>Circular</u> <u>Letter No.</u> <u>8</u> and Supplements <u>No. 1, No. 2</u>	3/20/2020 4/22/2020 6/26/2020	Provider Flexibilities	Suspends various utilization review requirements and requires expedited payment of hospital claims. EXPIRED June 18, 2020; however, certain preauthorization requirements were temporarily reinstated per Circular Letter No. 17 (see below).	EXPIRED June 18, 2020.	
DFS Circular Letter No. 10 and DFS 60 th Amendment to Insurance Regulation 62	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.	EXPIRED on May 26, 2021.	
DFS <u>Circular</u> <u>Letter No. 17</u>	12/23/20	Provider Flexibilities	 Directs insurers to suspend the following requirements: Preauthorization review for urgent or non-elective scheduled inpatient surgeries, hospital admissions, and transfers between hospitals; Preauthorization review for inpatient rehabilitation and home health care services following an inpatient hospital admission; Preauthorization review for inpatient mental health services following an inpatient hospital admission; and 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. 	EXPIRED February 21, 2021.	

VACCINE AND MASK MANDATES

Regulatory Agency	Status	Vaccine Mandate	Mask Mandate
Centers for Medicaid and Medicare Services (CMS) and Centers for Disease Control and Prevention (CDC)	CMS mandate in effect.	CMS <u>requires</u> all listed health care facilities participating in Medicare or Medicaid to require any staff who might come into contact with patients to be fully vaccinated against Covid-19 (i.e., to have received a one-dose Covid-19 vaccine or two doses of a two-dose vaccine). Religious or medical exemptions may be offered.	N/A (see CDC mask guidance here).
Occupational Safety and Health Administration (OSHA)	WITHDRAWN effective January 6, 2022	OSHA directed all companies with more than 100 employees to require staff to be vaccinated, with an option for regular testing. Religious and medical exemptions were permitted. OSHA withdrew the mandate following a U.S. Supreme Court decision rejecting the rule.	N/A
New York State (NYS) Department of Health (DOH)	Vaccine requirements made permanent on June 22, 2022. However, they are not currently being enforced due to a pending court challenge. DOH's mask mandate in health care settings EXPIRED on	 DOH regulations require all staff at covered health care providers to be vaccinated, with no testing opt-out or religious exemption. The covered provider types include: Article 28 licensed hospitals, nursing homes, and diagnostic and treatment centers (DTCs); Article 36 home health agencies; and Article 40 hospices; and adult care facilities. The U.S. Supreme Court refused to block the vaccine requirement despite challenges. However, on January 17, 2023, a New York judge struck down the vaccine mandate. DOH has filed a notice of appeal seeking to overturn the decision. 	Effective February 12, 2022, following the expiration of State's emergency mask mandate in health care settings, DOH issued guidance directing all personnel (regardless of vaccination status) in a health care setting regulated under Articles 28, 36, and 40 of the Public Health Law, to wear an appropriate face mask in accordance with CDC guidance here. This guidance is based on transmission levels rather than Covid-19 community levels, and apply to all personnel and visitors above the age of 2 that are medically able to tolerate a face covering/mask. Facilities not regulated under these articles are also strongly encouraged to adhere to these recommendations. Facilities operating under the authority of another State agency should follow the masking requirements of that agency.

	February 12, 2023.		Adult care facilities (ACFs) should follow CDC community <u>guidance</u> and CDC <u>guidance</u> for congregate living settings.
New York City (NYC)	effective November 1, 2022.	NYC Mayor Bill de Blasio issued an Emergency Executive Order directing all NYC-based private employers to require workers to be vaccinated. Medical and religious exemptions may be offered, including accommodations to allow unvaccinated employees to submit to regular Covid-19 testing. There were some exceptions for employees that worked remotely, individuals entering the covered premise for a quick a limited purpose, and individuals under five years of age, among others.	N/A
NYS Office of Mental Health (OMH)	OMH emergency regulations and CMS mandate in effect and applicable as noted.	 The CMS mandate applies to: OMH operated or licensed hospitals and Comprehensive Psychiatric Emergency Programs (CPEPs), which should be in compliance with OMH's emergency rule requiring vaccines at such facilities; and OMH-licensed Residential Treatment Facilities (RTFs) for youth. The mandate does not apply to OMH-licensed facilities that are not certified by CMS, such as clinics, rehabilitation programs, and residential programs that are not operated by a hospital. OMH's emergency regulation require staff to be fully vaccinated against Covid-19 at hospitals and secure treatment facilities. 	OMH encourages all staff in health care settings to wear an appropriate face mask in certain circumstances, in accordance with CDC guidance. OMH further notes that agency leadership may determine to require masking for staff and/or clients in particular programs when there is an outbreak of Covid-19 or other infectious respiratory diseases.

NYS Office of Addiction	CMS mandate	The CMS mandate <u>applies</u> to OASAS	Effective September 7, 2022, pursuant to DOH
Services and Supports	in effect and	certified, funded, or otherwise authorized	requirements, masks are <u>required</u> for staff and
(OASAS)	applicable as noted. OASAS has not yet updated masking guidance following the expiration of DOH requirements.	 programs/facilities that are operated by Article 28 hospitals, including: 816 Withdrawal and Stabilization Services; 818 Substance Use Disorder Inpatient Rehabilitation Services; and 822 Outpatient Services (including outpatient rehabilitation and Opioid Treatment Programs). The mandate does not apply to community-based programs. 	patients in 816, 817, 818, and 822 programs, regardless of vaccination or booster status. Should staff and patients choose to mask in 819 and 820 programs and/or the programs opt to go beyond this guidance and require masking, both are permissible. If 816/818 and 819 or 820 programs are co-located in the same building and using the same entrance, then consideration should be given to strongly recommending masking for all staff and patients. Such decisions should be delineated in the program's infection control policies and procedures.
NYS Office for People with Developmental Disabilities (OPWDD)	CMS mandate in effect and applicable as noted.	 The CMS mandate applies to the following OPWDD facilities: Intermediate Care Facilities, including OPWDD's developmental centers; Specialty Hospitals; and Article 16 clinics (to the extent the facility is enrolled in Medicare under 42 CFR 485.725). The CMS mandate does not apply to Home and Community-Based Services (HCBS), Health Homes (CCOs), Crisis Services for Individuals with Intellectual and Developmental Disabilities (CSIDD), Independent Practitioner Services for Individuals with Developmental Disabilities (IPSIDD), and 100% State-funded programs. 	Effective September 7, 2022, OPWDD no longer requires masks to be universally worn in OPWDD certified or operated programs. Specialty Hospitals must follow DOH and CDC requirements.

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.

Final Regulations

DOH finalized telehealth regulations in the September 14, 2022 State Register (available <u>here</u>). The final regulations add a new Part 538 to Title 18 of the New York Codes, Rules, and Regulations (NYCRR), outlining state reimbursement for telehealth services. The regulations:

- Expand 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
- Add 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.

DOH plans to release a guidance document outlining permanent changes to telehealth regulations following the Covid-19 pandemic, which will be released as a special edition of the Medicaid Update.

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 (currently set to end on May 11, 2023), 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.

Effective January 2023, the flexibilities to waive or suspend the Annual Re-Assessment and Significant Life Event Re-Assessment for Home and Community Based Services (HCBS) Level of Care (LOC) eligibility determinations **have immediately ended**. As a result, Children's Health Home Care Managers (HHCM) and Children and Youth Evaluation Services (C-YES) assessors must ensure that all currently enrolled and eligible

members of the HCBS Children's Waiver have a timely Annual Re-Assessment and a Significant Life Re-Assessment (when necessary) within 2023. If the member's annual Re-Assessment was due in January 2023, the care manager has until the end of February 2023 to complete the re-assessment. Additional details are available in DOH guidance here.

Effective January 1, 2023, children's respite services flexibility have **expired**, including the ability to bill for services delivered via telehealth. Additional details are available here.

Effective April 1, 2023 the following Health Home flexibilities will **end/be modified** as follows:

- Plans of Care must be signed by the member/parent/guardian/legally authorized representative, and verbal consent is no longer permitted (signatures may be collected on paper forms or electronically);
- Plans of Care and Comprehensive Assessments must be completed within 60 calendar days of Health Home enrollment;
- Multidisciplinary/care team meetings are no longer waived and must be conducted upon request of the member/family, or as determined by the care manager (may be conducted in-person or virtually as determined by the member/parent/guardian/legally authorized representative);
 and
- Consent to share information must be provided in writing, either collected on paper forms or electronically, and verbal consent in lieu of a signature is no longer permitted.

Additional details are available here.

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

- DOH Policy on Controlled Substances During the PHE
- 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 June 1, 2023.

Final Regulations

OMH finalized new regulations on telehealth in the September 28, 2022 State Register <u>here</u>, that 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 <u>here</u>. SPG's summary of the regulations is available <u>here</u>. OMH is also finalizing edits to a telehealth guidance document expected to be released shortly.

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 February 2, 2023, OMH issued guidance on prescription of controlled substances after the federal PHE (available here). The guidance indicates that, without further federal action, at the conclusion of the PHE programs must ensure practitioner compliance with the Ryan Haight Act, as follows:

- Patients who have been seen in-person prior to or during the PHE by the practitioner prescribing the controlled medication may continue to be prescribed such medications using telehealth.
- Patients who have never been seen in-person must be seen in-person by the prescribing practitioner at least once prior to the renewal or new prescription for a controlled substance after the PHE ends. The guidance strongly encourages programs to begin scheduling in-person appointments before the end of the PHE to manage practitioner workload and mitigate risk to patients.
- Patients who were seen in-person prior to or during the PHE, but have their medications prescribed by another practitioner (the covering practitioner), must be seen in-person by the prescribing practitioner within two years of the last in-person visit.

On February 14, 2023, OMH released a revised Covid-19 infection control manual (available here) that includes updated information on masking requirements.

Office of Addiction Services and Supports (OASAS)

On June 25, 2021, OASAS issued a regulatory waiver 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 January 20, 2023).

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, 2022, 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).
- Permit Medication Assisted Treatment (MAT) induction via telehealth.
- Extend minimum time requirements required for telehealth billing.

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.

Other Guidance

OASAS has released the following guidance documents for providers:

- Continuing Covid-19 Regulatory Flexibility
- Continued Covid-19 Regulatory Waivers
- Guidance on Mask Wearing requirements in 816, 817, 818, and 822 Certified, Funded, or Otherwise Authorized Settings
- Covid-19 Infection Control Guidance for Non-Hospital-Based Inpatient and Residential Addiction Treatment Providers
- Staff Return to Work Attestation
- Antigen Testing in Inpatient and Residential Settings and Opioid Treatment Programs
- Residential and Inpatient Addiction Treatment Program Reopening Guidance
- Return to Work Guidance
- Reopening Guidance for Opioid Treatment Programs

• Reopening Guidance for Prevention Services Programs

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, 2021, 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 federal PHE.

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

- Revised Protocols for the Implementation of Isolation and Precaustion for Individuals Exposed to Covid-19 in OPWDD Certified 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

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 for the duration of the federal PHE and continues to provide certain authorizations and exemptions for many professions and activities related to the ongoing Covid-19 emergency response.

FEDERAL POLICIES

On February 9, 2023 CMS published a fact sheet (available <u>here</u>) laying out a "Transition Roadmap" for policy changes that will result as the end of the PHE. Notably, the guidance notes that the following policies will not immediately change:

- <u>Vaccinations and Products</u>: Medicare, Medicaid, and most regulated private insurers will still be required to cover Covid-19 vaccinations. Existing Emergency Use Authorizations (EUAs) issued by the Food and Drug Administration (FDA) for Covid-19 products will remain in effect.
- <u>Medicare and Medicaid Coverage of Testing</u>: Medicare Part B will continue to cover tests without cost-sharing, as will Medicaid programs through September 30, 2024.
- <u>Telehealth</u>: Most current Medicare telehealth flexibilities will remain in place through December 2024. State Medicaid programs have discretion over telehealth coverage and their permanent policies will not be affected by the end of the PHE.

Notable policies that will be changing include:

- Telehealth Prescription of Controlled Substances: Under the PHE, the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) are allowing DEA-registered practitioners to prescribe controlled substances to patients without an inperson interaction. Although this policy will end with the PHE, CMS states that "there will be rulemaking that will propose to extend these flexibilities" and that DEA "will provide additional guidance to providers soon." In the interim, New York has issued guidance indicating that providers will need to be in compliance with pre-emergency requirements after the PHE (see above).
- <u>Blanket Waivers and Disaster Waivers:</u> In general, blanket waivers issued by CMS will expire with the PHE. Medicaid waivers issued under 1915(c) Appendix K, Medicaid Disaster Relief State Plan Amendments, and other authorities will also expire with the PHE or shortly thereafter, as well as Section 1135 waivers. CMS is expected to continue updating provider-specific documents (available here) outlining which flexibilities will expire.
- <u>HIPAA Enforcement Discretion</u>: Guidance relaxing enforcement of data privacy and security under the Health Insurance Portability and Affordability Act (HIPAA) will expire with the PHE.
- <u>Private Coverage of Testing</u>: The requirement for private insurance companies to cover tests without cost sharing, both for OTC and laboratory tests, will end.
- <u>Hospital Reporting</u>: Hospital data reporting will continue as required by the CMS conditions of participation through April 30, 2024, but reporting may be reduced from the current daily reporting to a lesser frequency.

Medicare

Current Status of Telehealth Waivers

Medicare's Covid-19 telehealth policies and flexibilities remain in effect for the duration of the PHE, 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 <u>added</u> 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.

Medicare Telehealth After the End of the PHE: Temporary Extension

In December 2022, Congress passed and President Biden signed an omnibus spending bill (Consolidated Appropriations Act, 2023) that extends certain Medicare telehealth flexibilities through December 31, 2024, if the Covid-19 PHE ends before this date. These are:

- The removal of geographic restrictions (related to rural areas and originating sites) on Medicare reimbursement;
- The reimbursement of telehealth services provided by occupational therapists, physical therapists, speech language pathologists, and audiologists;
- The reimbursement of federally qualified health centers (FQHCs) and rural health centers for telehealth services (at non-PPS rates);
- The delay of the Medicare requirement for practitioners to hold an in-person visit with any beneficiaries receiving telehealth for mental health services within six months of starting treatment, and every year thereafter;
- The reimbursement of audio-only services that are identified to be appropriate by CMS; and
- The ability to use telehealth to conduct a "face-to-face" encounter prior to recertifying a Medicare enrollee's eligibility for hospice care.

The bill also requires HHS to submit a report that would examine the effects of telehealth expansion on Medicare spending and utilization. The full bill text is available here.

The Medicare list of allowable telehealth services is available <u>here</u>. The list now includes:

- Services that are permanently authorized (on a "Category 1" or "Category 2" basis); and
- Services that are temporarily authorized due to the Covid-19 PHE, which may fall into two types:
 - o Services whose authorization will expire 151 days after the end of the PHE;
 - Services that are considered "likely to have clinical benefit" and are therefore approved to be provided through telehealth on a "Category 3" basis, which authorizes them through December 31, 2023

The list also identifies which services may be provided on an audio-only basis. These generally include:

- Mental and behavioral health services, such as psychotherapy and counseling;
- Certain chronic condition and care management codes, such as diabetes management;
- Nutrition services;
- Speech and hearing therapy;
- "Phone E&M" codes added for the PHE.

Some of these services are permanently authorized for telehealth, while some are not; regardless, they should continue to be available to provide as audio-only services as long as they are authorized to be provided through telehealth.

CMS confirmed in the 2023 Physician Fee Schedule rule (finalized in November 2022) that it intended for Category 3 authorizations for telehealth services to lapse at the end of December 2023. However, it also stated that "in the event that the PHE extends well into CY 2023, we may consider revising this policy." Therefore, if the expiration date for Category 3 services were to be extended, it could be proposed in the CY 2024 Physician Fee Schedule rule in the spring or summer of 2023.

Medicare Telehealth After the End of the PHE: Mental Health

The 2020 Consolidated Appropriations Act (CAA) permanently expanded the availability through telehealth of certain mental health services to Medicare enrollees, with restrictions. Specifically, Medicare geographic restrictions will not apply to services provided to patients with whom a therapist has an existing and ongoing in-person relationship. 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.

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.

At the conclusion of the PHE, PREP Act liability protections for countermeasure activities that are not related to any U.S. Government agreement (e.g., products entirely in the commercial sector or solely a state or local activity) will end unless another federal, state, or local emergency declaration is in place for area where countermeasures are administered. HHS is currently reviewing whether to continue to provide this coverage going forward.