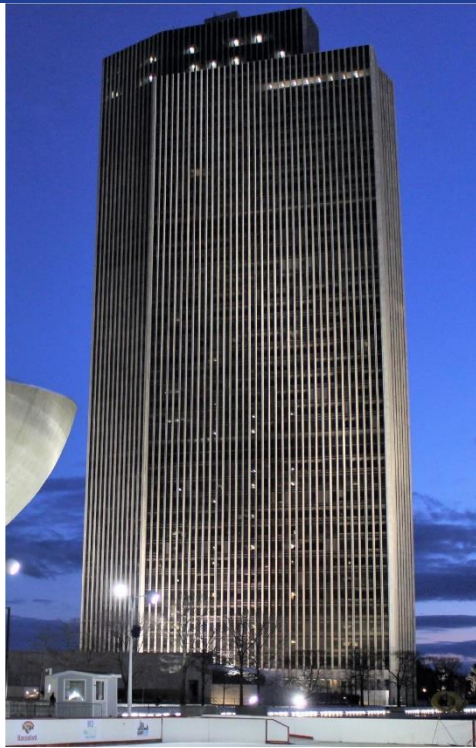


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PLUGGED IN TO HEALTH

Healthcare & Policy Coverage Across New York State



June 29, 2021

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New York Ends COVID-19 State Disaster Emergency



On June 23, 2021, Governor Andrew M. Cuomo **announced** that New York’s state disaster emergency related to the COVID-19 would end, beginning on June 25th. The state disaster emergency was first declared on March 7, 2020, more than fifteen months ago.

Under the Governor’s most recent **Executive Order #210**, the Executive Orders (“EOs”) 202 through 202.111 and EOs 205 through 205.3 are rescinded and deemed “no longer necessary”. Though the temporary directives and suspensions of law and regulation pursuant to these EOs are no longer in effect, several state agencies may be issuing guidance or emergency regulations to assist with the transition of more complex operational regulatory and statutory requirements.

The **federal guidance** from the Centers for Disease Control and Prevention (“CDC”) remains in effect for unvaccinated individuals, requiring the use of face masks when unable to practice social distancing, and for all rider on public transit and in other sensitive settings, such as health care, nursing homes, correctional facilities, and homeless shelters.

DOH Issues Guidance Relating to the End of the State’s Disaster Emergency

The Department of Health (“DOH”) has issued the following guidance to assist with the transition of more complex operational regulatory and statutory requirements related to COVID-19 laboratory testing that reflects the recent Executive Order (“EO”) #210 which ends NY’s state of emergency related to COVID-19.



- **Pharmacists** – The EO permitting licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited-service laboratory (“LSL”) that performs COVID-19, influenza virus and respiratory syncytial virus testing, has been discontinued effective June 25, 2021. Pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, pharmacists may continue to order and administer COVID-19 diagnostic tests, provided that a new director who meets the State’s definition for qualified healthcare professional (NYS licensed physician, dentist, podiatrist, physician assistant, specialist

assistant, nurse practitioner, or midwife) is identified, and a completed **Change in Laboratory Director** form must be submitted to the DOH within 30 days of receipt of this guidance.

- **Physician Office Laboratories** (“POLs”) – While EO 202.72 is now expired, POLs performing COVID-19 testing in New York State must continue to adhere to reporting requirements mandated by CMS. DOH is directing laboratories to continue to submit laboratory testing results directly to the ECLRS within 24 hours of performing the test which allows NYS to also meet Federal requirements.
- **Temporary Collection Stations** (aka - patient service centers or PSC) – EO 202.1 permitting a clinical laboratory to operate temporary collection stations is now expired, and any laboratory that is operating a PSC that has not obtained Department approval, must submit a request for a new PSC to the Department within 30 days of receipt of this guidance. Application materials for a new PSC and additional information can be found **here**.

OMH – Commissioner’s Regulatory Waiver

On June 25th, the Office of Mental Health (“OMH”) issued a **Regulatory Waiver**, granting temporary relief to COVID-19 affected regulated entities from certain NYS regulatory requirements within Chapter XIII of Title 14 of the NYCRR (Office of Mental Health) that are not otherwise required by State or Federal law. The regulatory requirements which are waived allow providers to meet local service needs and serve the best interests of service recipients while maintaining program quality and integrity and to ensure the rights, health and safety of service recipients will not be diminished.

Among other things, the waiver allows for the following:

- the continued use of telehealth with certain exceptions;
- the suspension of certain required provider internal, written utilization review procedures;
- waives certain minimum service duration timeframes to permit providers to bill for provision of services;
- reduced documentation requirements and timeframes associated with initial treatment plan development and treatment plan reviews; and
- the continued waiver of physician authorization renewals requirement for residential programs.

This waiver will remain in effect for 60-days.

OASAS – Continuing COVID-19 Regulatory Flexibilities

The Office of Addiction Services and Supports (“OASAS”) has issued **guidance and waivers** to continue certain COVID-related statutory and regulatory flexibilities for OASAS programs as they relate to New York's COVID-19 public health emergency which ended on June 25, 2021.

This guidance directs OASAS providers to resume routine processing of background checks, in accordance with 14 NYCRR Part 805, for all prospective employees, including all staff members hired on and after June 24, 2021. For those background checks which

were abbreviated under interim guidelines, additional measures are required as outlined under this guidance.

This guidance also outlines certain telehealth flexibilities by temporary waiver of certain regulatory provisions including the definitions of distant and originating sites, as well inclusion of Certified Recovery Peer Advocates as authorized practitioners permitted to deliver telehealth services, and methods for delivering secured telehealth services to include telephonic only. Additionally, the guidance also continues flexibilities which expand the list of permissible telehealth services, the waiver of an initial in-person evaluation, the waiver of the telehealth application process, and the waiver of certain minimum time requirements for service delivery.

Additional Regulatory Flexibilities – OASAS issued a series of COVID related guidance documents which allow for regulatory flexibility in a variety of areas. Such regulatory flexibilities will continue until August 25, 2021 while OASAS evaluates what, if any, additional regulatory flexibility must be extended to providers.

COVID-19 Vaccination Guidance



On June 24th, the DOH issued revised guidance to enrolled providers of the **COVID-19 Vaccination Program** which includes updates regarding the extended shelf life for the Johnson & Johnson’s Janssen single-shot COVID-19 vaccine (J&J vaccine) from 3 months to 4.5 months (an additional 6 weeks), as authorized by the U.S. Food and Drug

Administration (“FDA”) on **June 10, 2021**. Vaccine providers that have J&J vaccine in storage should visit **<https://vaxcheck.jnj>** and enter the lot number to confirm the latest expiration dates of vaccine and must be updated in the NYSIIS or CIR inventory module.

COVID-19 vaccines that are authorized under an Emergency Use Authorization (“EUA”) do not have fixed expiration dates, and their expiration dates may be extended per FDA review, and vaccine providers should check the manufacturer’s website to obtain the most up-to-date expiration dates for on-hand supplies.

In addition, to ensure all New Yorkers can find vaccination locations close to them, vaccine providers are ***strongly encouraged*** to have their facility/facilities opt-in to the CDC’s online VaccineFinder tool (**[Vaccines.gov](https://www.vaccines.gov)**). Additional information on the VaccineFinder tool can be found **[here](#)**.

Second COVID-19 Vaccine Doses: This guidance updates providers who have insufficient vaccine to administer a second dose that was delayed beyond the 42-day window should work with their local health department, rather than the Regional Hub Hospital as was advised in the past. This updated guidance also details **special considerations** for individuals receiving COVID-19 vaccine outside the United States.

Separate and apart from the above updated guidance, the DOH has also issued guidance reminding providers of the reporting requirements to NYSIIS and CIR, as a condition of

receiving federally funded vaccine. The Department's **[NYSIIS/CIR Reporting Requirements for the COVID-19 Vaccination Program](#)** guidance is available by clicking **[here](#)**.

CMS Releases 2021-2022 Medicaid Managed Care Rate Development Guide

The Centers for Medicare & Medicaid Services (“CMS”) has released its **[2021-2022 Medicaid Managed Care Rate Development Guide](#)** for use in setting rates for rating periods starting between July 1, 2021, and June 30, 2022 for managed care programs subject to the actuarial soundness requirements in federal regulations (42 C.F.R. § 438.4).

CMS states that this rate development guide builds upon the Medicaid Managed Care Rate Development Guide effective for rating periods that start between July 1, 2020, through June 30, 2021, along with the experience of states and CMS in completing rate certifications and reviews, but this rate development guide does not replace or revise the guidance in place for those prior rating periods.

This guide is comprised of three sections. The first section applies to all Medicaid managed care capitation rates. The second section outlines specific concepts that states and their actuaries must consider when developing rates that include long-term services and supports (LTSS). The third section focuses on issues specific to new adult group capitation rates. Additionally, Appendix A outlines information regarding the accelerated rate review process and procedures. If states or their actuaries have questions regarding this guidance, they may contact **MMCratesetting@cms.hhs.gov**.

eMedNY Updates

eMedNY has provided updated information for Pharmacy Providers enrolled in the State's Medicaid Program under the following links on the eMedNY website.

- **[Prospective Drug Utilization Review / Electronic Claims Capture and Adjudication \(ProDUR/ECCA\) Provider Manual](#)**
 - **[Medicaid Fee-for-Service Program - Pharmacy Manual Policy Guidelines](#)**
-

Regulatory Update

Department of Financial Services (DFS) –

[Waived Cost-sharing of COVID-19 Vaccine](#) – The DFS has ***re-issued*** **[emergency regulations](#)** that require health insurers to provide coverage, with no cost-sharing, of COVID-19 immunizations and the administration thereof when provided by participating and non-participating health care providers. This rule applies to authorized insurers and health maintenance organizations that issue a policy or contract providing hospital, surgical, or medical care coverage, including a

grandfathered health plan. Coverage of COVID-19 immunizations and their administration must be provided immediately upon the earlier of the following events:

1. The issuance by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices of a recommendation for the COVID-19 immunization;
2. The issuance by the U.S. Preventive Services Task Force of a recommendation with an "A" or "B" rating for the COVID-19 immunization; or
3. The determination by the Superintendent of Financial Services, in consultation with the Commissioner of Health, that a policy or contract must cover the COVID-19 immunization.

This rule is valid through September 22, 2021.

Department of Health (DOH) –

Enforcement of Social Distancing Measures – The DOH has issued further **revised emergency regulations** for enforcement of social distancing measures that reflect the State's adoption of CDC guidance regarding use of face masks and fully vaccinated individuals along with the end of the COVID-19 state of emergency in New York. Specifically, these regulations update the DOH's **previously filed emergency regulations** (dated June 22, 2021), to remove the language which authorizes the regulation to apply for the duration of any state disaster emergency declared related to the outbreak of COVID-19 in New York State. This rule is effective for 60-days from June 23, 2021.

Telehealth Services – The DOH has issued emergency regulations which continue the authorization for all Medicaid providers to utilize telehealth, including audio-only telephone or other audio-only technologies beyond the end of COVID-19 state of emergency. This continued authorization of Medicaid telehealth services will allow for continuity in care after certain flexibilities provided under Executive Orders related to NY's COVID-19 state of emergency, which are no longer in effect after June 24, 2021.

Surge and Flex Health Coordination System – The DOH has **re-issued** emergency regulations authorizing the DOH Commissioner to suspend or modify certain provisions of the State Sanitary Code and other regulations for Article 28 facilities, Adult Care Facilities (ACFs), and assisted living facilities during a declared state disaster emergency to be consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. This regulation establishes and authorizes the Commissioner to activate a Surge and Flex Health Care Coordination System ("Surge and Flex System") in the event of a declared state disaster emergency which includes the following requirements.

- Increased bed capacity by a minimum of 50%, and up to 100% in some cases, to include service category changes, physical plant changes, as well as the restriction, or postponement, of non-essential, elective procedures to facilitate the increase.
- Enhance staffing capacity, which facilities must establish plans that ensure any increase in bed capacity is met with adequate staffing, where such criteria for staffing is at the discretion of the Commissioner.
- Minimum levels of supplies and personal protective equipment (PPE) must be met, maintained and managed by facilities, with at least a 90-day supply of PPE, where such PPE may be re-distributed under the authority of the Commissioner.

- A statewide coordination of facilities, including the discharge, transfer, and receipt of patients among various facilities, as well as the designation of trauma centers, and the maintenance of a Statewide Health Care Data Management System.

The regulations also require each Article 28 facility to adopt a detailed emergency Surge and Flex Response Plan (“Plan”), in addition to their standard emergency and disaster preparedness plan. The Plan must be implemented and meet the requirements of the Surge and Flex System among other criteria and emergency preparedness requirements. Facilities must renew and update the Plan as needed, or a minimum of every six months, as well as attest that the plan may be implemented and achieved upon each review.

Lastly, the regulation also authorizes the Commissioner to take necessary action to expand and prioritize clinical laboratory testing during the declared state disaster emergency.

This emergency rule is effective as of June 24, 2021, through August 8, 2021.

Hospital Personal Protective Equipment (PPE) Requirements

and

Nursing Home PPE Requirements – The DOH has **re-issued** these emergency regulations relating to the establishment and maintenance of minimal levels of personal protective equipment (PPE). All hospitals must possess and maintain a 90-day supply of PPE, and all nursing homes must possess and maintain a 60-day supply of PPE, beginning September 30, 2020, unless the facility applied for and was granted an extension by the DOH. The regulations provide that failure to maintain the prescribed supply of PPE may result in the revocation or suspension of the facility’s license, provided that the DOH permit the facility a 14-day grace period only in the event of a facility’s first violation.

These emergency regulations are effective as of June 24, 2021, through August 8, 2021.

COVID-19 Vaccinations of Nursing Home and Adult Care Facility

Residents and Personnel – The DOH has **re-issued** emergency regulation requiring that nursing homes and adult care facilities (ACFs) in New York State meet certain minimum requirements related to the vaccination of unvaccinated residents and unvaccinated facility personnel. This **updated** emergency regulation differs from the previous emergency regulation, such that the regulation is no longer subject to apply for the duration of the state’s COVID-19 state of emergency, along with the changes identified below in **bold** font.

Requirements for nursing homes:

- Prior to April 29, offer all consenting, unvaccinated existing personnel and residents an opportunity to receive the first or any required next dose of the COVID-19 vaccine.
- Ensure that all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility has an opportunity to receive the first or any required next dose of the COVID-19 vaccine within fourteen days of having been hired by or admitted or readmitted to such facility, as applicable.

- The above requirements shall also include posting of related signage throughout the facility, provide a written affirmation to be signed for those residents and personnel who were offered the opportunity to be vaccinated though declined. The nursing home must also certify to the DOH ***in a manner and frequency prescribed by the Commissioner, but in no event more often than weekly***, that they have proactively offered all new unvaccinated residents and personnel the opportunity to obtain the COVID-19 vaccine within a 14-day period as specified above.

Requirements for ACFs (AHs, EHPs, Adult Residences, and ALRs):

- Prior to April 22, make diligent efforts to arrange for all consenting, unvaccinated existing personnel and residents to register for a vaccine appointment, and document the attempts and methods used to schedule the vaccine in the individual's personnel file or case management notes, as applicable.
- Must arrange for the COVID-19 vaccination (the first, and any required next dose) for all new personnel, including employees and contract staff, and every new resident and resident readmitted to the facility. This regulation also outlines pre-admission and pre-employment screening practice requirements to determine an individual's interest in obtaining the COVID-19 vaccine and any necessary vaccine scheduling efforts for the ACF to undertake.
- All required ACFs must certify to the DOH ***in a manner and frequency prescribed by the Commissioner, but in no event more often than weekly***, that they have proactively offered all new unvaccinated residents and personnel the opportunity to obtain the COVID-19 vaccine within a 7-day period as specified above. ACFs must provide a written affirmation to be signed for those residents and personnel who were offered the opportunity to be vaccinated though declined.

Further, this regulation is also updated such that a facility found in violation of these regulation will be subject to ***penalties in accordance with sections 12 and 12-b of the Public Health Law***. This emergency regulations are effective as of June 24, 2021, through August 8, 2021.

DOH Public Notices:

Nursing Home Case Mix Index ("CMI") – The DOH issued two Public Notices regarding the State's intent to propose a State Plan Amendment ("SPA") to the CMS.

The case mix index used to adjust the direct component price for nursing home services to Medicaid beneficiaries will be based on all Medicaid-only case mix data submitted by NYS nursing facilities to CMS which is applicable to the previous six-month period (e.g., April – September for the January case mix adjustment; October – March for the July case mix adjustment).

The DOH states that this amendment allows for the inclusion of all assessments submitted by nursing homes which will achieve a higher degree of accuracy in case mix reimbursement, and the reimbursement will be appropriate for the acuity levels. The DOH estimates the annual net aggregate decrease to gross Medicaid expenditures attributable to the proposed change in case mix methodology is \$132 million for State Fiscal Year 2022.

The public is invited to review and comment on this proposed State Plan Amendment, a copy of which will be available for public review on the Department's website:

https://www.health.ny.gov/regulations/state_plans/status/

Legislative Update

Now that the 2021 Legislative session has ended, bills that have passed both houses of the Legislature will be delivered to the Governor in “batches” over the next several months. Once a bill has been delivered to the Governor, he has 10 days (excluding Sundays) to either sign the bill into law or veto the bill.



Coming Up

Thursday, July 15, 2021 @ Time TBD – **Public Health and Health Planning Council, Committee Day** – Via [Webcast](#)

Thursday July 15, 2021 @ 9:00 a.m. – **Drug Utilization Review Board Meeting** – Via [Webcast](#)

Quick Links

[NYS Department of Health](#) --- [NYS DOH – Quick Links](#)[Meetings, Hearings & Special Events](#) --- [Medicaid Redesign Team](#) --- [Senate Health Committee Website](#) --- [Assembly Health Committee Updates](#) --- [NYS Division of Budget](#)

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