

Topic	Federal	New York State
Laboratory/Testing	<p>April 28th: FDA has now approved 50 Emergency Use Authorizations (EUA) for COVID-19-related tests. This includes 8 serological antibody tests approved for laboratories with a high or medium complexity CLIA certification and 3 molecular tests that are CLIA waived for use in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance.</p> <p>April 21st: FDA approved the first COVID-19 test for patient at-home sample collection. This approval is a reissuance of the EUA for LabCorp’s COVID-19 RT-PCR test, using LabCorp’s at-home collection kit.</p> <p>April 1st: FDA authorized the first EUA for a serological test, the Cellex, Inc. qSARS-CoV-2 IgG/IgM Rapid Test. The serological test can detect the presence of antibodies in asymptomatic persons. Other serological tests are being handled as described below.</p> <p>March 30th: CMS issued an interim rule which states that, for the duration of the emergency, it will reimburse hospitals, laboratories, and other entities for performing tests for COVID-19 on people at home and in other community-based settings outside of the hospital. Health systems and communities may set up special sites for this purpose. Hospital EDs may set up drive-through and off-campus sites for screening, including non-EMTALA-compliant sites.</p> <p>The FDA has now approved a total of 20 EUAs, including real-time and point-of-care test.</p> <ul style="list-style-type: none"> • FDA will not object to the distribution and use of tests by other manufacturers after validation while an EUA request is being prepared. FDA believes 15 business days should be a reasonable amount of time to grant this flexibility. • FDA will not object to any use of serological tests for COVID-19 testing, as long as the test is validated, FDA has been notified, and a disclaimer is included that the FDA has not reviewed the test and such tests should not be used as the sole basis for determining infection status. • FDA has put in place a general policy for states to approve authorization of tests developed and used by laboratories in their states without further consulting the FDA. New York was the first to receive this type of authorization (March 13th). 	<p>April 28th: The statewide COVID-19 antibody survey has now tested 7,500 New Yorkers, and the infection rate is now estimated at 14.9%. The antibody survey will be expanded this week to focus on a sample size of 6,000 first responders, including: 1,000 NYPD officers; 1,000 FDNY officers; 3,000 frontline health care workers; and 1,000 transit workers. Antibody testing for frontline health care workers in New York City will be conducted at Bellevue Hospital, Elmhurst Hospital Center, Montefiore Medical Center and SUNY Downstate Medical Center. The State also plans to expand the scope of diagnostic testing as capacity increases. As of April 26th, it has expanded statewide diagnostic testing criteria to include asymptomatic first responders, health care workers, and essential employees.</p> <p>April 23rd: Governor Cuomo announced preliminary results of the antibody study conducted this week on 3,000 New Yorkers across 19 counties. Preliminary results indicate that 13.9 percent of the sample tested positive for COVID-19 antibodies, which would translate to an estimated 2.7 million people infected statewide. The Governor noted that this number may lower the estimated death rate to approximately 0.5 percent, with the caveat that at-home deaths and other deaths that were not confirmed to be COVID-19 related are not included in the calculation. The preliminary results confirm regional disparities across the State, with significantly higher infection rates in the downstate area.</p> <p>April 20th: NYSDOH will today begin a statewide antibody testing survey that will randomly sample 3,000 New Yorkers to determine the percentage of the population that may have acquired COVID-19 immunity. The results of this survey are expected to inform the “reopening” process by which the State will loosen social distancing regulations.</p> <p>April 17th: Governor Cuomo issued Executive Order 202.19, which directs DOH to establish a single statewide coordinated testing protocol. All laboratories in the state would be required not to conduct COVID-19 testing except according to that process.</p> <p>April 11th: DFS released guidance (available here) for health insurers on coverage requirements during the COVID-19 emergency. The guidance indicates in particular that the waiver on COVID-19 testing and associated medical visits (by in-network providers or any emergency department) means that the issuer will reimburse the provider for the patient’s cost-sharing requirements, including copayments and deductibles.</p> <p>April 5th: The State’s highest daily testing capacity is now up to 23,000 people tested.</p> <p>March 29th: The State’s Wadsworth Lab developed a new, less intrusive test for COVID-19 that uses a saliva sample and can be self-administered.</p> <p>March 27th: New York State is now testing about 16,000 to 18,000 people per day.</p> <p>March 16th: Healthcare providers may request COVID-19 testing at the Wadsworth Center or order from clinical laboratories when patients who meet at least one of the following criteria:</p> <ul style="list-style-type: none"> • A person has come within proximate contact (same classroom, office, or gatherings) of another person known to have tested positive for COVID-19 OR • A patient shows symptoms of illness and has traveled from a country for which the CDC has issued a CDC Level 2 or 3 Travel Health Notice within 14 days of illness onset OR

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Telehealth	<p>April 10th: CMS stated that Medicare Advantage (MA) organizations and other organizations that submit diagnoses for risk adjusted payment will be able to submit diagnoses for risk adjustment that are from telehealth visits when those visits meet all other criteria for risk adjustment eligibility. As such, the visits must be for an allowable inpatient, outpatient, or professional service and stem from a “face-to-face” encounter. In this context, telehealth services provided using an interactive audio and video telecommunications system that permits real-time interactive communication, e.g., a smart phone, will satisfy the face-to-face requirement.</p> <p>April 5th: CMS released a brief informational video on the Medicare telehealth expansion, available here.</p> <p>March 30th: CMS’s interim rule also expands the scope of telehealth services in Medicare:</p> <ul style="list-style-type: none"> • About 80 new CPT codes may be billed via telehealth, including ED visits, hospital services, nursing facility services, home visits, neonatal and pediatric critical care, intensive care services, psychological testing, physical and occupational therapy, and others. • Medicare will reimburse for telephone (audio-only) consultations with practitioners (medical and non-medical) using CPT codes 98966-98968 and 99441-99443. • Virtual check-ins and remote patient monitoring may be offered to both new and established patients. • E-visits may be delivered by behavioral health practitioners and therapists. • Frequency limits on certain telehealth services have been lifted (subsequent inpatient/SNF visits and critical care consults). <p>March 27th: The third federal COVID-19 response bill, the CARES Act, contains a number of provisions expanding the availability of telehealth:</p> <ul style="list-style-type: none"> • For the duration of the emergency, Federally Qualified Health Centers (FQHCs) may serve as distant sites to provide telehealth to Medicare beneficiaries. They will be reimbursed at rates comparable to the Medicare physician fee schedule, not the special FQHC rate. • For the duration of the emergency, the Medicare restriction on telehealth which limits providers to provide services to patients they have served in the last three years has been removed. • Restrictions on the use of telehealth in home health and hospice services have been lifted. • High-deductible health plans (which make individuals eligible for a Health Savings Account) would be allowed to cover telehealth pre-deductible. • \$200 million is provided to the Federal Communications Commission’s Connected Care Pilot program to facilitate telehealth. <p>March 17th: CMS has expanded telehealth services for Medicare beneficiaries, as permitted by the federal COVID-19 response bill passed on March 6th. Starting on that date, services delivered by telehealth to a Medicare beneficiary are reimbursable regardless of geographic restrictions or originating site limitations. In particular, this includes services delivered to beneficiaries in non-rural areas and/or located in their own homes. Also, Medicare cost-sharing may be waived by providers, and CMS will not enforce the</p>	<p>OMH—April 28th: OMH released clinic billing guidance (available here) that relaxes time requirements for certain services and provides guidelines for billing for services provided via telehealth to dual eligibles. For dual eligibles, Medicare-enrolled providers are permitted to crossover Medicare telehealth and telephonic claims to Medicaid using the Medicare-required codes. Providers not recognized by Medicare (LMSWs, LCATs, etc.) may bill Medicaid directly using the clinic APG codes with the telehealth modifier.</p> <p>OMH—April 16th: OMH issued an updated FAQ discussing questions on telemental health. Previously OMH issued a waiver allowing all Article 31 licensed programs to offer services via telehealth (including telephonic) during the COVID-19 emergency. Providers may include paraprofessionals and unlicensed behavioral health staff, but if a license is required, they must be licensed in NYS. Providers must self-attest that they will meet operating standards, use a secure telehealth system, maintain confidentiality, and use appropriate telehealth modifiers in billing. Approval occurs upon submission of the self-attestation form. OMH also waived the need for an initial assessment conducted in-person before providing services. This guidance does not apply to Community Residences, Adult BH HCBS Short-Term Respite and Intensive Crisis Respite, nor to private practitioners operating outside of an OMH-licensed or designated service.</p> <p>DFS—April 11th: The DFS guidance mentioned above (available here) also discusses the similar waiver of cost-sharing for telehealth, which was established in March 16th guidance for all services (whether or not COVID-19-related) reimbursed by Medicaid and commercial insurers.</p> <p>OPWDD—April 10th: OPWDD released updated guidance on the delivery of services via telehealth, which states that all nonresidential facilities and programs certified or operated by OPWDD are permitted and encouraged to be delivered via telehealth to individuals with I/DD, whenever possible. Health and habilitation services may be delivered via telehealth (including telephonic) unless the service requires the physical presence of a staff member for the health and safety of the individual (e.g., residential habilitation or live-in caregiver). Telephonic transmission is not permissible for respite services.</p> <p>DOH—March 31st: DOH released a Medicaid Telehealth FAQ document that provides comprehensive answers to questions across a range of topics, including billing guidelines, patient and provider locations, practitioner types, documentation requirements, and children’s services. A number of important issues are clarified, including:</p> <ul style="list-style-type: none"> • Article 28 clinics may bill for telemedicine (audio-video) services provided by their employed practitioners who are at home. • Details about the types of staff who may bill for patient assessment and management have been clarified (including FQHC social workers, home care aides, therapists, and so on). • For dual eligibles, NYS Medicaid will continue only to cover services that are covered by Medicare, and it will reimburse applicable Medicare coinsurance or deductibles for such services. In particular, services such as psychotherapy (which Medicaid will reimburse when provided telephonically for non-dual eligibles) will not be reimbursed if provided telephonically to dual

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	<p>requirement that patients have a prior relationship with the telehealth provider. During this period, Medicare will make payments for allowable telehealth codes (listed here). The telehealth visits are considered the same as in-person visits and will be paid at the same rate. Providers may also continue to provide the virtual check-in services and e-visits that they were previously able to offer.</p> <p>HHS has notified providers that they may use any non-public facing remote communication product to provide telehealth, whether related to COVID-19 or not, without facing penalties for noncompliance with HIPAA. This includes non-specialized video chat applications, such as Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, and Skype.</p>	<p>eligibles. The FAQ does not yet address the new CMS rules released Monday evening that create Medicare reimbursement for telephonic visits through CPT codes 98966-98968 and 99441-99443.</p> <p>DOH—March 27th: A revised Medicaid Update states that NYS Medicaid will now reimburse any covered service provided telephonically, as long as it is appropriate to be delivered by telephone. This includes:</p> <ul style="list-style-type: none"> - Evaluation and management (E&M) services by medical professionals; - Assessment and patient management by all other Medicaid professionals, whether through fee schedule or by rate; - Offsite E&M by clinics, ambulatory surgery centers, or other programs; - Offsite E&M by Federally Qualified Health Centers (FQHCs); and - Any other appropriate service. <p>Services may be provided to new or established patients. Telehealth services will be reimbursed at parity with existing off-site visit payments (clinics) or face-to-face visits (i.e., 100% of Medicaid payment rates).</p> <p>OASAS—March 13th: OASAS issued a waiver that modifies certain telepractice regulations to allow current providers to more rapidly deliver services via telepractice (including telephonic) and permits all providers to offer services via telepractice for the duration of the COVID-19 emergency. Providers who do not already have approval for telepractice must self-attest that they will meet qualification standards, use a secure and credible technology system, maintain confidentiality, provide culturally competent translation services as necessary, develop a contingency plan, and use appropriate telehealth modifiers in billing. Services to be delivered are those allowable under current program regulations or State-issued guidance as clinically appropriate and include assessment, individual, group, medication management and collateral services. Peer support services are currently not included.</p>
Provider Licensure and Oversight	<p>April 22nd: CMS issued new blanket waivers for long-term care hospitals (LTCHs), intermediate care facilities for individuals with intellectual disabilities (ICFs/IDD), federally qualified health centers (FQHCs) and rural health centers (RHCs), and other types. The new waivers have been added directly to CMS’s list of blanket waivers (available here). Waived requirements include:</p> <ul style="list-style-type: none"> • Certain site-neutral payment rate provisions for LTCHs; • Provisions that limit FQHCs and RHCs from establishing temporary expansion locations without approval; • The requirement that patients in an inpatient rehabilitation facility receive 15 hours of therapy per week; • The LTCH 25-day average length of stay requirement (already waived, but now expanded to facilities that are seeking to become LTCHs); • Staffing regulations, community outings requirements, mandatory training requirements, and rules around active treatment for ICFs; and • The 60-day limit that a physician or physical therapist may use a single substitute (extended to the length of the COVID-19 emergency plus 60 days). <p>April 3rd: HHS OIG will be answering questions from providers about waived requirements, including the below-mentioned self-referral waiver. Questions about how OIG would view a specific arrangement may be sent to OIGComplianceSuggestions@oig.hhs.gov.</p> <p>March 30th: CMS’s interim rule provides blanket waivers of sanctions under the Physician Self-Referral Law for any financial relationships or referrals related to COVID-19. For example, for the duration of the</p>	<p>April 27th: The Governor issued Executive Order 202.24, which authorizes licensed pharmacists to order COVID-19 tests approved by the Food and Drug Administration (FDA) to detect SARS-CoV-2 or its antibodies, and to administer COVID-19 tests after completion of appropriate DOH training.</p> <p>April 16th: Governor Cuomo issued Executive Order 202.18 expanding permissions for out-of-state health care personnel and health care personnel from Canada to practice in New York State, and allowing nurse practitioners to practice in a hospital or nursing home for 180 days immediately following graduation.</p> <p>April 9th: Governor Cuomo issued Executive Order 202.15 allowing medical students who have graduated from medical programs in New York State in 2020 to practice in New York State under supervision.</p> <p>April 7th: Governor Cuomo issued Executive Order 202.14 allowing medical students who are slated to graduate in 2020 and who have been accepted to a residency program to begin practicing immediately under supervision.</p> <p>April 3rd: DOH has released guidance related to how providers should respond to health plan waivers of utilization review requirements.</p> <p>March 30th: Governor Cuomo issued Executive Order No. 202.13 which allows employees of programs licensed or certified under State agencies (OPWDD, OCFS, OASAS, or OMH) who have previously undergone the appropriate background checks to be employed by a program under a different State agency without undergoing new background checks.</p>

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	<p>waiver, physicians will be exempt from sanctions if they refer patients to a home health or ambulatory surgery center in which they have a financial interest. The rule also:</p> <ul style="list-style-type: none"> • Waives various screening requirements for practitioner and supplier enrollment, such as site visits and background checks; • Delay all revalidation actions; • Will not require Medicare FFS medical review; and • Waives requirements for proof of delivery for Part B drugs and DME. <p>March 27th: HHS has issued a total of 34 emergency 1135 waivers to states. The approved provisions include:</p> <ul style="list-style-type: none"> • Suspending Medicaid FFS prior authorization requirements; • Rolling over existing prior authorizations; • Suspending PASRR (nursing home) assessments for 30 days; • Extending timeframes for Medicaid fair hearings; • Waiving certain requirements for non-enrolled out-of-state providers to serve a State’s Medicaid enrollees; • Allowing facilities (nursing homes, ICFs, etc.) to be reimbursed if residents are relocated from the facility in an emergency; and • Offering increased flexibility around submitting SPAs, such as waiver of public notice. <p>March 13th: HHS issued a nationwide blanket 1135 waiver authorizing Medicare, Medicaid, and CHIP regulations to be waived, notably including:</p> <ul style="list-style-type: none"> • Certain certification requirements for provider participation; • Requirements that practitioners must hold licenses in the State in which they provide services; and • Stark law sanctions. 	<p>March 27th: Governor Cuomo issued Executive Order 202.11 which allows recent nursing graduates to practice under the supervision of a registered professional nurse and allows midwives licensed in any state or Canada to practice in New York without penalty.</p> <p>March 23rd: Governor Cuomo issued Executive Order 202.10 which allows for additional health care personnel to practice or volunteer at facilities, including: radiologic technologists and respiratory therapists licensed in any state, graduates of foreign medical schools with relevant experience, students on track to become licensed health care professionals, and physician assistants, registered professional nurses, licensed practical nurses, and nurse practitioners without registration in New York State or without oversight from or a collaborating agreement with a physician. The Executive Order also expands EMS capabilities, removes limits on working hours for physicians, and relieves health care providers from recordkeeping requirements as necessary.</p> <p>March 20th: OPWDD guidance states that medical practitioners (physicians, registered nurses, licensed practical nurses, nurse practitioners, or physician assistants) delivering telehealth services may be licensed in any state.</p> <p>March 18th: Governor Cuomo issued Executive Order 202.5, which will allow the waiver of requirements that various provider types have an in-state license to practice in New York. This includes physicians, physician assistants, nurse practitioners, registered nurses, and licensed practical nurses.</p>
Public Health Measures	<p>March 29th: President Trump announced that the federal government will extend the federal nationwide social distancing guidelines through April 30th.</p> <p>March 16th: The CDC is now recommending:</p> <ul style="list-style-type: none"> • Working from home whenever possible; • Avoiding all social gatherings of more than 10 people; • Prohibiting visitors to long-term care facilities unless for critical assistance; • Delaying elective medical procedures (ambulatory visits, surgeries, etc.) 	<p>April 27th: The Governor said that NY on PAUSE, which is currently in effect until May 15th, may end as of that date in some regions. The decision will be made based on factors such as a 14-day decline in hospitalization rates, health care facility capacity, business precautions in place, and testing/tracing efforts.</p> <p>April 16th: Governor Cuomo announced that NY on PAUSE will be extended through May 15th. Executive Order 202.17 requires all individuals to cover their nose and mouth with a mask in a public place if adequate distance cannot be maintained (except infants under 2 years of age and those who are medically incapable).</p> <p>April 6th: Governor Cuomo announced during a press conference that NY on PAUSE social distancing requirements would remain in effect through April 29th, and fines for individuals who violate such protocols would increase to a maximum of \$1,000.</p> <p>March 30th: Executive Order 202.13 extends the timeframe during which non-essential employees must work from home and in-person businesses will be restricted until April 16th.</p> <p>March 27th: Executive Order 202.11 authorizes police to remove individuals who are in violation of rules on public gatherings or other space usage. Schools will continue to be closed through April 15th.</p> <p>March 20th: Governor Cuomo announced a set of measures called NY on PAUSE, which include that 100% of the workforce, excluding essential services (a list of which is available here), must work remotely. He</p>

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		<p>also recommended that all New Yorkers stay indoors as much as possible, with the exception of solitary exercise or essential activities, and take other necessary precautions.</p> <p>March 16th: The Governor announced a unified set of public health measures being taken by New York, New Jersey, and Connecticut, including banning gatherings of more than 50 people, closing various public-facing businesses by 8pm, and closing schools for at least two weeks (beginning March 18th).</p>