NEW YORK STATE OF OPPORTUNITY. Department of Health

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Jackie Glaze
CMS Acting Director
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61 Forsythe St SW Suite 4T20
Atlanta, GA 30303-8909
Via email transmittal to Jackie.Glaze@cms.hhs.gov

Re: **New York State: Medicaid 1135 Waiver Request**

Dear Ms. Glaze:

By way of this letter, the State of New York requests that the Centers for Medicare & Medicaid Services ("**CMS**") grant waivers of certain federal health care laws in response to the public health emergency caused by the outbreak of 2019 Novel Coronavirus ("**2019-nCoV**" or "**COVID-19**"). As background for this request, we acknowledge and appreciate that, on January 31, 2020, in anticipation of the effects of COVID-19, Secretary of Health and Human Services Alex Azar declared a public health emergency pursuant to Section 319 of the Public Health Services Act. Secretary Azar's declarations were retroactively effective to January 27, 2020. On March 13, 2020, as authorized under Title V of the Stafford Act, President Donald J. Trump declared a national emergency in response to the effects of the 2019-nCoV. On March 13, 2020, Secretary Azar issued his formal waiver approval authority under Section 1135 of the Social Security Act ("**Section 1135**").

As authorized under Section 1135, New York is requesting waivers of certain federal Medicare, Medicaid, CHIP, EMTALA, and HIPAA authorities to ensure that sufficient health care items and services are available to meet the needs of our state residents, managed care plans, and providers. These waivers will give New York the flexibility to implement changes, as needed, to address any urgent health care needs of our residents. As CMS is aware, on March 7, 2020, Governor Andrew M. Cuomo signed Executive Order No. 202 Declaring a Disaster State of Emergency for the entire State of New York due to the outbreak of COVID-19 in the State. Under the terms of the Executive Order, since amended to reflect the changing nature of the outbreak and the State's rapid responses to these changes, certain State laws were suspended or waived and State agencies have been instructed to take all reasonable efforts to assist in the response and recovery. These responses are informed by the fact that New York has the highest number of confirmed cases in the country at 20,875. As of March 22, 2020, the New York State Department of Health ("**DOH**") reports that there have been 5,707 new confirmed cases of COVID-19 and 157 resulting deaths.

Background

The response to the COVID-19 outbreak by our providers, local districts, health plans, and communities has been extraordinary. New York has taken swift action to increase its testing capacity and, as of the date of this letter, has approved 28 private laboratories to test for the virus. The State also stood up drive-through testing centers throughout the state to increase its testing capacity, a model which is being replicated in other states. The first center opened in

New Rochelle (Westchester County), the state's original hotspot, and subsequent locations have opened in three additional counties, as well as one location on Staten Island. The State is also planning to use a 1,000-bed Navy hospital ship in New York Harbor, which will significantly increase New York's hospital surge capacity.

Through a series of Executive Orders and other executive actions, to reduce density across the State and to slow the spread of the virus, Governor Cuomo has directed all local governments to allow non-essential personnel to work from home, and similarly directed non-essential state workers to do the same. Schools have also been closed through mid-April and through the Governor's "New York State on PAUSE" orders, all non-essential businesses must close. This includes bars and restaurants (excepting take-out/delivery), casinos, gyms, theaters, malls, amusement parks, and businesses providing personal care services (i.e., barbershops, hair salons, tattoo parlors, etc.). Further, non-essential gatherings of any size are to be cancelled or postponed. Notwithstanding these incredible efforts, New York requires regulatory relief from CMS to help enhance and ensure the success of this ongoing work through the State's Medicaid program, which provides essential health coverage for more than 6.2 million New Yorkers.

New York is working to implement the "blanket" waivers announced by CMS on March 13, 2020 in Medicaid and CHIP, to the extent applicable, as well as the expansions to telehealth benefits similar to what was announced by CMS on March 17, 2020. In addition, New York expects its licensed facilities and providers to operate under all CMS blanket waivers announced by CMS on March 13, 2020. The purpose of this letter is to outline both our intended use of the blanket waivers and the approval of additional waivers New York requests from CMS approval, consistent with CMS's authority under, and within the scope of, Section 1135.[1] Given that we are still analyzing and evaluating the HHS-authorized blanket waiver authorities, and additional (and very helpful) guidance and regulatory flexibilities continue to be issued affirmatively by CMS, some of the additional waivers we request in this letter may be obviated due to their coverage under your blanket waivers or subsequent guidance.

Although our intent is to utilize the HHS-authorized blanket waivers to the extent possible, we also do not want to overlook any important or emerging issues that could enhance the response to this public emergency. Based on this preferred utilization of blanket waivers, and the rapidly evolving response to COVID-19 in New York, we ask that CMS acknowledge that New York, similar to other states, will likely be required to make supplemental 1135 Waiver requests to the extent that we identify items that are not encompassed by new or existing blanket waivers, this waiver request, or other requests being advanced by DOH or our partner agencies under state plan amendments, 1915(c) Waiver Appendix K requests, or other disaster-related legal authorities. Consistent with the message advanced during CMS's All-State Call on March 17, 2020, New York appreciates CMS's emphasis on flexibility during the pendency of this public health emergency, and we look to partnering with CMS to ensure the most accommodating and appropriate responses possible to help alleviate the enormous burden being placed on the health care system in our state and across the country.

[1] Given the rapidly evolving nature of the State's response to COVID-19, New York notes that inclusion of a specific waiver request within this letter is not an assurance or guarantee that New York will necessarily implement that request, if granted by CMS.

Requested 1135 Waivers

New York is seeking to avail itself of the already approved 1135 Waivers as described in CMS's "COVID-19 Emergency Declaration Health Care Providers Fact Sheet." Additionally, on March 13, 2020, Secretary Azar issued a Section 1135 declaration, authorizing the waiver and/or modification of certain requirements, but only to the "extent necessary, as determined by the Centers for Medicare and Medicaid Services." To that end, New York State is requesting approval from CMS for New York State to implement the waivers and/modifications set forth in the above referenced declaration by Secretary Azar. Further, as indicated above, there are additional flexibilities consistent with CMS's authority under Section 1135 that are essential to New York's effective response to the COVID-19 public health emergency, which have also been set forth in this letter for CMS's consideration.[2] For ease of reference, we have organized our requests by subject matter and issue.

A. Provider Screening and Enrollment.

As previously permitted by CMS and in approved 1135 Waivers for other states, New York requests waiver of the following screening and enrollment requirements set forth in 42 C.F.R. Part 455 and related sub-regulatory guidance for providers enrolled or who seek to be enrolled in the New York Medicaid Program:

- Temporarily waiving payment of application fee to enroll a provider on a temporary basis;
- Temporarily waiving criminal background checks associated to enroll a provider on a temporary basis;
- Temporarily waiving site visits to enroll a provider on a temporary basis;
- Temporarily waiving the requirement that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have equivalent licensing in another state or foreign jurisdiction, or are licensed by Medicare and the hold the required professional licensure in New York;
- Temporarily suspending pending enforcement or termination action or denial of payment sanction to a specific provider;
- Temporarily waiving the limits to the instances of care and how many participants may receive care in a 180-day period from out-of-state providers not enrolled in New York's Medicaid program;
- Temporarily suspending the requirements that Medicaid Managed Care and CHIP health plan network providers must enroll in the State's Medicaid program;
- Temporarily ceasing revalidation of providers who are located in New York or are otherwise directly impacted by the emergency;
- Providing payments to facilities for providing services in alternative settings, including an unlicensed or temporary facility, if the provider's licensed facility has been evacuated, compromised, is inadequate to meet the demand as determined by the state or the facility or is necessary to protect the health and safety of other patients; and
- Otherwise streamlining provider enrollment requirements when enrolling providers.

[2] New York is in the process of submitted an Appendix K under its 1915(c) Waivers, including the Office for People with Developmental Disabilities Comprehensive Home and Community Based Service Waiver (NY 0238.R06.00) and the NY Children's Waiver (NY 4125.R05.00) for additional flexibilities and funding related to the COVID-19 Public Health Emergency. New York is also in the process of examining State Plan Amendment and using other waiver authorities to help aid the State in its response to this unprecedented public health emergency.

B. Hospital Requirements.

As previously permitted by CMS, we ask that CMS waive the following regulatory requirements regarding the administration and operation of hospital facilities, diagnostic and treatment facilities, and other licensed health facilities in the State, where applicable:

- Allowing hospitals to house inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute inpatient care but may not meet federal life safety requirements;
- Allowing hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients from the excluded distinct part psychiatric units to acute care beds and units if required as a result of the emergency;
- Allowing hospitals with excluded distinct part inpatient rehabilitation units to relocate inpatients from the excluded distinct part rehabilitation units to acute care beds and units if required as a result of the emergency;
- Allowing Inpatient Rehabilitation Facilities ("**IRFs**") to exclude patients from the hospital's or unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60 percent rule") if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such;
- Allowing a long-term care hospital ("**LTCH**") to exclude patient stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement, which allows these facilities to be paid as LTCHs;
- Allowing Medicare Inpatient Prospective Payment System ("**IPPS**") excluded inpatient psychiatric units and IRFs serving inpatients to access comprehensive payments without a CMS case-by-case review where the State has approved use of these locations; and
- Waiving the following requests for Medicare appeals in Fee for Service, Medicare Advantage and Part D:
    - Extension to file an appeal;
    - Waive timeliness for requests for additional information to adjudicate the appeal;
    - Processing the appeal even with incomplete Appointment of Representation forms but communicating only to the beneficiary;
    - Process requests for appeal that do not otherwise meet the required elements using information that is available; and
    - Utilizing all flexibilities available in the appeal process as if good cause requirements are satisfied.

Similar to other states, New York seeks waiver authority on behalf of hospitals for the following Conditions of Participation ("**CoPs**") or federal regulatory requirements, which would enable hospitals to respond more effectively to the nationwide public health emergency:

- *Discharge Planning* (42 C.F.R. §§ 482.43(a)(8) & 485.642(a)(8)). Enable hospitals to discharge patients who no longer need acute care based solely upon which post-acute providers that can accept them without sharing the data requested by the regulators;
- *Physical* Environment (42 C.F.R. § 482.41; A-0700 *et seq*.). Permit hospitals: (1) to use technology and physical barriers that can serve as the backbone for isolation and quarantine systems, and offer other ways to limit exposure and potential spread of the virus, such as through the use of video and audio resources for limiting direct contact between physicians and other providers in the same facility; and (2) to arrange for

treatment to occur in non-hospital buildings and patient vehicles, assuming patient safety and comfort. As mentioned above, New York, in conjunction with many of its facilities are standing up drive through specimen collection and testing sites, such that New York seeks permission for basic evaluation and treatment be allowed in patient vehicles in order to prevent potential spread of the virus to the facility and ensure that existing hospital space can be used for medical care and treatment.

- *Patient Rights* (42 C.F.R. § 482.13). Waive enforcement of patient rights related to personal privacy, confidentiality (see HIPAA request below), orders for seclusion, and patient visitation rights.
- *Sterile Compounding* (42 C.F.R. § 482.25(b)(1) & USP 797). Permit face masks to be removed and retained in the compounding area, such that they can be re-donned and reused during the same work shift only. This flexibility will conserve scarce face mask supplies and will help with the impending shortage of medications.
- *Verbal Orders* (42 C.F.R. §§ 482.23 and 482.24, A-0407, A-0454, A-0457). Permit that verbal orders may be used more than "infrequently" (i.e., read-back verification is done) and authentication may occur later than 48 hours. This flexibility will allow for more efficient treatment of patients in a surge situation.
- *Reporting Requirements* (42 C.F.R. § 482.13(g)(1)(i)-(ii), A-0214). Extend reporting requirements for ICU patients whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs beyond the close of the next business day, provided any death where restraint may have contributed is continued to be reported within standard time limits.
- *Medical Staff* (42 C.F.R. § 482.22(a); A-0341). Permit physicians and other medical staff whose privileges will expire and new physicians and other medical staff to practice before full medical staff/governing body review and approval. This waiver will keep these clinicians on the front line and allow hospitals and health systems to prioritize patient care needs during the emergency, especially when many medical staff offices are understaffed.
- *Medical Records Timing* (42 C.F.R. § 482.24; A-0469). Extend the timeline for full completion of medical records beyond 30 days following discharge. This waiver will allow clinicians to focus on the care needs at hand, while completing the necessary paperwork as the crisis wanes.
- *Observation Beds* (42 CFR § 440.2). Suspend the 24-hour limit on observation services and permit payment for hospital outpatient observation services up to 48 hours, if not longer, especially for patients who have been admitted from a nursing home or SNF, and who are awaiting testing before returning to the nursing home or SNF. Permitting this reimbursement will encourage that these patients are treated quickly and do not occupy hospital beds that may become scarce during a surge in COVID-19 cases.
- *Bed Increases and Swing Beds.* Enable hospitals to increase its number of certified beds, as necessary to respond to the public health emergency, and enable hospitals that do not have either a hospital-based skilled nursing facility ("**SNF**") or a swing bed unit to use their acute care beds to provide SNF level care if the public health emergency should require it.
- *Offsite Billing* (42 C.F.R. § 440.90). Permit hospitals and other licensed health care facilities, including diagnostic and treatment centers, clinics that service people with intellectual and development disabilities, and mental health clinics, to bill for services delivered in off-site locations beyond current exception for individuals or families experiencing homelessness.

Given the significant number of world class academic medical centers in our state, New York seeks additional flexibility and consideration by CMS for academic medical centers. Unique to the graduate medical education ("**GME**") context and the specific needs of these academic medical centers, two waivers would help combat the spread of COVID-19:

- *Physical Presence Requirement*. Medicare GME billing rules under 42 C.F.R. § 415.172 require that a training physician be "physically present" during the critical or key portions of the procedure performed by a medical resident in order for services to be billed under the Medicare Physician Fee Schedule by the teaching physician. CMS should clarify that this physical presence requirement may be satisfied through telehealth or telephonic modalities permitted by federal or state telehealth guidance specific to COVID-19.
- *Indirect Medical Education*. 42 C.F.R. § 412.105 calculates Indirect Medical Education ("**IME**") reimbursement to the ratio of residents to beds within a hospital facility. Given that these IME ratios will likely change during the pendency of the nationwide public health emergency as bed counts increase and hospital facilities are reconfigured, New York seeks for a "hold harmless" or similar protections to the IME reimbursement paid to academic medical centers based on swings in bed counts that will likely accompany the public health response.

C. Health Insurance Portability and Accountability Act (HIPAA) requirements.

New York appreciates the flexibility afforded by the recent Notification of Enforcement Discretion for telehealth remote communications during the COVID-19 nationwide public health emergency on March 17, 2020. The ability to use video chat applications and other electronic media that facilitate telehealth will be an invaluable tool in detecting and treating patients in our communities. New York is also requesting waiver authority to temporarily suspend the application of sanctions and penalties arising from non-compliance with HIPAA requirements related to the following actions (as authorized in Secretary Azar's March 13, 2020 declaration):

- Obtaining a patient's agreement to speak with family members or friends (45 CFR § 164.510);
- Honoring a request to opt out of the facility directory (45 CFR § 164.510);
- Distributing a notice (45 CFR § 164.520);
- The patient's right to request privacy restrictions (45 CFR § 164.522); and
- The patient's right to request confidential communications (45 CFR § 164.522).

We also seek confirmation that this blanket waiver authority is intended to extend for the duration of the nationwide public health emergency, rather than only 72-hours from when a covered entity implements its emergency response.

In addition to the waivers already afforded by Secretary's Azar's declaration, New York requests the following waivers and flexibility requests with regard to HIPAA, which have not been previously discussed, but would prove invaluable in addressing the staffing and resource challenges caused by the nationwide public health emergency:

- *Access to Records.* Under 45 C.F.R. § 164.524(c)(2)(i), offering flexibility to HIPAA Covered Entities for the duration of the nationwide public health emergency when fulfilling requests by individuals for access to their PHI. Specifically, we request that Covered Entities be permitted to offer access electronically, rather than in paper even if

requested by a patient, based on the inability of Covered Entities to have access to printing capabilities while working remotely.

- *Breach Notification.* The breach notification requirements under 45 CFR Part 164, Subpart D contain specific timeframes for investigation and notification of a potential breach involving unsecured PHI and then written notification of affected individuals by first-class mail. Given the limited resources available to Covered Entities to investigate potential breaches of unsecured PHI, as well as the ability to print and mail notices and comply with these breach notification requirements within the prescribed timeframes, New York requests that CMS permit Covered Entities to deliver breach notification communications electronically, whenever possible, and to extend the breach notification times for the duration of the public health emergency.
- *Valid Authorizations.* Under 45 C.F.R. § 164.508(c)(1), HIPAA requires that authorizations for release or certain uses of PHI be obtained through a signed written document. Given the difficulty of obtaining hard copy, signed authorizations based on staffing and access shortages, and the importance of ensuring that authorized PHI may be transmitted as directed by a patient, New York requests that CMS permit Covered Entities to rely on verbal authorizations as documented in the individual's record as a valid authorization during the nationwide public health emergency.
- *Code Sets.* Similar to other states, New York is requesting that CMS waive HIPAA EDI code set requirements under 45 CFR § 162.1002. This waiver would permit New York, as with other states, additional flexibility to define and implement code sets not currently available in a standard federal code set or provide additional specificity to a code set definition that allows us to track and set rates for services specific to COVID-19.

D. Emergency Medical Treatment and Labor Act (EMTALA) requirements.

As it pertains to EMTALA, New York requests the following blanket waiver that would temporarily suspend application of EMTALA sanctions for redirection of an individual to receive a medical screening examination in an alternative location or transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared emergency (as authorized in Secretary Azar's March 13, 2020 declaration). We also seek confirmation that this blanket waiver authority is intended to extend for the duration of the nationwide public health emergency, rather than only 72-hours from when an organization implements its emergency response. Without limiting the generality of the blanket waiver to EMTALA, specific EMTALA-related flexibilities are necessitated by the COVID-19 outbreak, including:

- *Alternative Screening Sites.* The use of alternative screening and triage locations for COVID-19 outside of a hospital's emergency department ("**ED**") or main campus, which could include drive-through screening and testing sites (such as those already established in New York), provider officers and urgent care centers, such that the spread of COVID-19 may be contained by directing patients seeking testing away from places where other patients congregate; and
- *Patient Transfers.* The ability of hospitals to transfer patients to other hospitals prior to stabilization according to protocols that account for COVID-19 diagnosis status or other circumstances, such as capacity demands, available resources, and expertise. This need to transfer patients is not limited to patients experiencing symptoms of COVID-19, but patients who present with other symptoms and may be more safely cared at other facilities with capacity and expertise.

E. Fair Hearings

Due to requirements on managed care plans and State offices to work remotely as much as possible, mailing and receipt of appeal case information; fair hearing evidence information; and fair hearing decision notices is being significantly delayed. New York does not have an electronic system to support such notification. Accordingly, New York is requesting a temporary extension of the time periods for managed care plans to resolve appeals, an extension of the 60-day timeframe for enrollees to exercise their plan appeal rights, and the suspension of the health plan requirement to authorize services within 72 hours of fair hearing decision to reverse a health plan determination.

F. Critical Access Hospitals (CAH)

New York requests a blanket waiver from CAH limits of beds to 25 and length of stay 96 hours.

G. Institutions of Mental Disease (IMD).

New York requests that CMS waive all IMD requirements, such that its providers may offer continuity of care for these individuals as demands from COVID-19 may make transfers more difficult or less timely.

H. Health Homes

New York requests that CMS waive all face-to-face requirements for Health Home Serving Adults, Health Homes Serving Children, and Care Coordination Organization/Health Homes and that CMS waive the requirements for written member consents and member signatures on plans of care and life plans; verbal consents would be documented in the member record. New York also requests that the annual assessment and the requirement to annually update the life plans/plan of cares be waived until further notification by the DOH.

I. Skilled Nursing Facilities (SNFs) and Long-Term Care

Similar to other states, New York requests a waiver of certain regulatory requirements regarding the administration and operation of SNFs, nursing homes, and other licensed long-term care providers in the State. As previously approved by CMS in other states, New York seeks a waiver of Level 1 and Level 2 Pre-Admission Screening and Annual Resident Review ("**PASRR**") assessments for 30 days as required under 42 CFR Part 483, such that all new admissions are able to be treated similar to exempted hospital discharges.

Additionally, New York has identified the following CoPs or other regulatory requirements related to the operation of SNFs, nursing homes, and long-term care providers that would benefit from a waiver and further flexibility during the pendency of the nationwide public health emergency:

- Allowing non-certified space to be used and reimbursed as a temporary SNF or nursing home, provided sufficient safety and comfort is provided for residents and staff, which will allow the State to open a temporary COVID-19 nursing facility to assist COVID 19 positive SNF or nursing homes residents to receive a nursing facility level of care and services during treatment for virus while protecting other vulnerable adults (42 C.F.R. Parts 409 and 483);

- Suspending the meeting of any resident groups to encourage social distancing and to ensure SNFs and nursing homes limit group activities within the resident population (42 C.F.R. § 483.10(f)(5));
- Extending the period over which an individual may work as a registered nurse aide beyond the four months limit permitted by federal regulations and spending performance reviews for certified nurse aides, as these actions will address SNF and nursing home workforce shortages over the course of the nationwide public health emergency (42 C.F.R. § 483.35(d));
- Allowing certified nurse aide students who have completed the nurse aide training program, but who have not yet completed the practicum due to closure of testing sites, to function as a certified nurse aide under the guidance and supervision of licensed nursing staff (42 C.F.R. § 483.35(d));
- Allowing nursing students who have completed at least one semester of classroom training to be allowed to function as a certified nurse aide after receiving expedited training and competency evaluation from a skilled nursing facility (42 C.F.R. § 483.35(d));
- Permitting all training requirements for certified nurse aides to be delivered online to avoid unnecessary contact during in-person trainings (42 C.F.R. § 483.152);
- Suspending required eligibility assessment for patients going from a SNF to home setting, which will expedite transfers of these residents to a safe home-based environment 42 C.F.R. § 484.55);
- Allowing certified nurse aides, home health aides, and personal care assistants to work across all long-term care setting, including nursing homes, assisted living programs, and home care (42 C.F.R. §§ 483.35 & 482.23);
- Extending minimum data set ("**MDS**") authorizations for nursing home and SNF residents and modifying the deadlines for conducting MDS assessments and transmissions to accommodate providers that are short-staffed and are focused on delivering safe care to their residents in this time of crisis (42 C.F.R. § 483.20);
- Suspending the three-day hospitalization requirement prior to Medicare-covered admission to skilled nursing facilities, which will decrease burdens on inpatient facilities if there is a surge in inpatient hospital admissions (42 C.F.R. § 409.30);
- Enabling certain beneficiaries who recently exhausted their SNF benefits to obtain renewed SNF coverage without first having to start a new benefit period, which will promote discharges from hospitals and permit flexibility to place an individual in the most appropriate and safest setting (42 C.F.R. Part 409); and
- Temporarily waiving requirements related to providing notice before transfers as facilities may not be able to comply during the public health emergency with the timelines for notice to residents, residents' designees, and ombudsman programs (42 C.F.R. § 483.15(c)(4)).

J. Community Based Long-Term Care Services and Community Based Mental Health, Outpatient, and Addiction Supports and Services

Similar to the flexibility sought for SNFs and nursing homes, New York seeks a waiver of the following requirements related to delivery of services by certified home care agencies and other providers of community-based long-term care services and supports ("**CBLTSS**") to New York residents:

- Temporarily suspending all face-to-face person-centered planning requirements, team meetings and plan of care signature requirements for provision of CBLTSS that are

otherwise required to initiate or continue services every 12 weeks (42 C.F.R. §§ 441.301(c)(3) & 540(c));
- Temporarily suspending two-week aide supervision requirement by a registered nurse for home health agencies (42 C.F.R. § 484.36);
- Permitting certified home health agencies to conduct a face-to-face encounter, which must occur within 90 days prior to the start of care, or within the 30 days after the start of care, by telephone or through telehealth modalities and relaxing the timeframes for compliance (42 C.F.R. § 418.110);
- Allowing Medicare Administrative Contractors to extend the auto-cancellation date of Requests for Anticipated Payment ("**RAPs**") during emergencies (42 C.F.R. § 484.205);
- Permitting home health agencies to perform certifications, initial assessments and determine patients' homebound status remotely via telephone or through telehealth modalities (42 C.F.R. § 484.55);
- Permitting "in-service" and "in-person" trainings to be conducted remotely or otherwise suspending this requirement, so that timeframes can be extended to complete trainings to avoid congregation of multiple individuals in a classroom setting (42 C.F.R. § 484.75(b)(9) and permitting any recertifications to be conducted through online competency evaluations (42 C.F.R. § 484.80);
- Suspending the requirement that home health aides be assigned to a specific patient by a registered nurse or other appropriate skilled professional (42 C.F.R. § 484.80(g)(1));
- Suspending annual in-home visits by a registered nurse or other appropriate skilled professional (42 C.F.R. § 484.80(h)(i)(iii)); and
- Extending deadlines for the submission of CMS Outcome and Assessment Information Set ("**OASIS**") until the end of the public health emergency (42 C.F.R. § 484.55).

Additionally, New York seeks authority under its State Plan, to the extent it does not already exist, to amend the Medicaid reimbursement for services delivered by community based mental health service providers. This waiver is required due to State mandates to minimize face-to-face contact and slow the spread of COVID-19. Accordingly, it is not possible for community based mental health providers to continue to provide site-based services under existing minimum contact standards or for the required minimum durations for the duration of the emergency. Currently, outpatient and rehabilitation behavioral health services are reimbursed under various federally approved methodologies which include monthly case payment, per diem, and per visit bases for claiming. In order to alleviate the immediate fiscal impacts associated with lost revenues and ensure community provider access and continuity of patient care during and after this crisis, the State requests authority to modify or eliminate contact standards within the following Medicaid services:

- Outpatient Clinic;
- Outpatient Rehabilitation;
- Opioid Treatment Programs;
- Peer Services;
- Medically Supervised Outpatient Withdrawal;
- Residential Rehabilitation Service for Youth;
- Residential Rehabilitation (Adults);
- Medically Supervised Residential Withdrawal;
- Assertive Community Treatment;
- Rehabilitative Services for Residents of Community-based Residential Programs;
- Personalized Recovery Oriented Services;
- Day Treatment services for Children;

- Continuing Day Treatment;
- Partial Hospitalization;
- Mental Health Clinic and Outpatient Hospital Services; and
- Children's EPSDT services including Other Licensed Professional, Crisis Intervention, Community Psychiatric Supports and Treatment, Psychosocial Rehabilitation Services, Family Peer Support and Services, and Youth Peer Support and Training services.

For the duration of the nationwide public health emergency, the State requests a waiver to modify or eliminate the minimum number of contacts required to submit claims for payment, shorten or eliminate the duration of minimum service encounters, and modify patient service plans in response to COVID-19. In addition, through this 1135 Waiver request or another waiver authority, such as Appendix K under a 1915(c) Waiver, New York seeks to reimburse providers for rehabilitative services to residents of community residents during a period of non-residence due to COVID-19. Similarly, to the extent the State determines that a provider of any of the services above cannot provide any services, including telephonic services, due to mandatory program closures due to COVID-19, the State requests authority to reimburse providers of such services.

K. Hospice

The blanket waivers issued by CMS did not directly address the critical role performed by hospice providers in delivering compassionate palliative care during this nationwide public health emergency. In addition to clarifying that hospice providers are specifically included in the categories of providers to which the blanket waivers apply, we ask that CMS afford these providers with additional flexibility to confront the challenges caused by COVID-19 through the following waiver requests:

- Extending deadlines for the collection and submission of the Hospice Item Set until the conclusion of the nationwide public health emergency (42 C.F.R. § 418.312);
- Suspending all face-to-face visit requirements by hospice physicians and nurse practitioners in favor of permitted telephone and telehealth modalities (42 C.F.R. § 418.22(a)(4));
- Extending the five-day timeframe for hospice providers to submit Notices of Election and Notices of Termination/Revocation (42 C.F.R. § 418.24);
- Encouraging all included hospice services to be provided by telephone and telehealth modalities, including bereavement counseling, social work, spiritual services, dietary services, and other counseling;
- Temporarily suspending the requirement of supervision of hospice aides by a registered nurse every 14 days for hospice agencies (42 C.F.R. § 418.76);
- Suspending the requirement for certified hospices to have a contract with a nursing home if a patient has moved (42 C.F.R. § 418.108);
- Suspending the requirement that hospices conduct background checks on employees with direct patient contact or access to records before hiring them, such that employees can be onboarded while the background check is processed (42 C.F.R. § 418.113);
- Suspending the volunteer requirements to reflect that many hospice volunteers, who tend to be elderly themselves, are not visiting patients and respecting limitations on social interaction (42 C.F.R. § 418.78(b)); and
- Limiting the provision of rehabilitative services, including physical therapy, occupational therapy, and speech therapy as these services tend to be limited in hospice care

generally, workforce challenges are becoming more acute, and the suspension of these services will serve to respect calls for limited social interaction.

L. Telehealth

New York appreciates the recently issued by blanket waiver under Section 1135 that expands when Medicare can pay for office, hospital, and other visits furnished via telehealth. We are also pleased to learn of the flexibility afforded by the Office of the Inspector General of the U.S. Department of Health and Human Services ("**OIG**") for health care provides to reduce or entirely waive cost-sharing for telehealth visits paid by Medicaid without risking a violation of the Anti-Kickback Statute or Civil Monetary Penalties Law. Building on this blanket waiver, New York seeks additional flexibilities regarding the use of telehealth in innovative and clinically meaningful ways to ensure that individuals are able to visit with their clinicians without putting themselves and others at risk of contracting or transmitting COVID-19. These additional flexibilities include:

- Allowing the use of telephonic, synchronous and asynchronous telehealth modalities for both new and established patients; and
- Suspending the federal requirements that in order to bill for a telehealth service a provider or a provider in their practice must have furnished a service to that individual within the previous three years so that telehealth codes can be billed even for first-time patients, many of whom will be using telehealth for the first time as the nationwide public health emergency.

M. Physician Referral

CMS guidance on Section 1135 Waivers expressly permits states to request that CMS waive sanctions under section 1877(g) of the Social Security Act (42 U.S.C. § 1395) relating to limitations on physician referrals (i.e., the Stark Law). New York requests such a waiver for hospitals and other designated health services as it pertains to certain actions taken by providers of designated health services to promote the most effective response possible to COVID-19. These actions may include, among others:

- Compensating physicians for unexpected or increased work demands outside the terms of an existing contractual or employment relationship (e.g., hazard pay);
- Encouraging health care systems to recruit additional practitioners from out-of-state or out of the country through provision of recruitment and retention payments that do not comply with current statutory and regulatory exceptions for these financial arrangements;
- Permitting donations of equipment, masks, or other resources to community physicians to help combat the spread of COVID-19; and
- Waiving penalties or productivity compensation reductions, even if not consistent with fair market value, to hold physician compensation constant and reflect the differential reimbursement for many telehealth services.

N. Laboratory Services

Laboratory testing capacity is a critical component of any response to the COVID-19 public health emergency. To promote sufficient clinical capacity within licensed clinical laboratories and to limit travel by pathologists and technicians, New York is seeking a waiver

Clinical Laboratory Improvement Amendment ("**CLIA**") requirements and regulations, such as the need to obtain CLIA certificates for locations where pathologists are working remotely using the laboratory's validated software.

O. Benefit and Authorization Requirements

The COVID-19 public health emergency has created unprecedented operational by the State and the Local Districts of Social Services that perform critical functions regarding determinations of Medicaid eligibility. To mitigate these difficulties, New York requests that CMS permit New York to implement certain additional changes to its eligibility determination processes:

- Consistent with 1135 Waivers granted to other states, including Washington and Florida, waive prior authorization and medical necessity processes in its fee-for-service program, to the extent New York applies these processes in our State Plan;
- Require fee-for-service providers to extend pre-existing authorizations through which a beneficiary has previously received prior authorization through the termination of the emergency declaration;
- Extend Medicaid eligibility beyond the end of the redetermination period for 12 months in order to maintain monthly caseloads at current levels;
- Not require certain conditions of eligibility that would require individuals to take action and provide documentation, including:
    - applying for other benefits, including but not limited to Medicare and Social Security benefits;
    - referrals for Veterans Benefits
    - providing documentation of available Third Party Health Insurance; and
    - referrals for cash medical support enforcement;
- Allow New York to apply a blanket documentation of our use of all exceptions for the duration of the nationwide public health emergency, in lieu of documentation in specific case records. This additional easement is essential because of diminished eligibility workforce following implementation of measures to combat the COVID-19 public health crisis; and
- Expand Hospital Presumptive Eligibility to include the over 65/aged & disabled population.

P. Managed Care

As CMS is aware, a majority of Medicaid beneficiaries access their services and supports through Medicaid managed care plans, including Managed Long-Term Care plans for individuals who are eligible for long-term support services and Health and Recovery Plans for individuals who are eligible for behavioral health services. Given the extent to which managed care is integrated into the fiber of the State's Medicaid program, New York is seeking several waivers from CMS under 42 C.F.R. Part 438 that recognize the input role these plans are playing in the response to the COVID-19 public health emergency. These waiver requests include:

- Revising current managed care contracts to add a reconciliation to reimburse managed care organizations for expenses related to COVID-19 and the emergency declaration;

- Permitting flexibility with requirements to complete credentialing of providers required under 42 C.F.R. § 438.214, which would align with waivers to the Medicaid fee-for-service enrollment requirement;
- Allowing members who have been out of the country for more than six weeks as a result of COVID-19 travel restrictions to maintain enrollment;
- Suspending the requirement for actuarially sound Medicaid managed care rates applicable to calendar years 2020 and 2021, such that the State may work with plans and their actuaries to best determine how to COVID-19 and its associated requirements regarding cost-sharing, telehealth, and other access requirements will impact plan financial performance;
- Waiving CMS's prior approval process under 42 C.F.R. § 438.6(c) for state-mandated MCO payments, to the extent that New York requires managed care plans to reimburse providers based on historic average revenue through a system other than claims and encounters; and
- Temporarily suspending the requirements under 42 C.F.R. § 438.66 of full on-site biannual operational, targeted, focused managed care surveys and readiness reviews and allowing partial completion of essential survey and readiness activities remotely.

As applied to Programs of All-Inclusive Care to the Elderly ("**PACE**") Organizations ("**PO**"), New York appreciates the guidance issued by CMS on March 17, 2020, which recognizes that that there "may be circumstances where a PO may need to implement strategies that do not fully comply with CMS PACE program requirements in order to provide benefits to participants while ensuring they are also protected from the spread of COVID-19." To that end, New York has identified the following specific needs of POs in the State and wanted to bring these flexibilities to the attention of CMS as part of this 1135 Waiver:

- Allowing a place or residence can include services provided at a temporary alternative site, such as a family member's home (CMS Call Letter (June 23, 2004) and February 2006 Guidance);
- Extending time periods for conducting the initial assessment and reassessments and permitting the substitution of telephone and telehealth modalities, rather than conducting these assessments and reassessments "in-person" (42 C.F.R. § 460.104);
- Permitting POs to maintain enrollment in cases where the enrollee was required to move out of the service area (42 C.F.R. § 438.56);
- Enabling emergency care to be provided outside of a written contract for PACE services (42 C.F.R. § 460.70); and
- Allowing interdisciplinary team assessments and reassessments, and in response to a request for service, relaxing scope of disciplines required (physician therapy, occupational therapy, etc.) to be completed (42 C.F.R. §§ 460.102-104).

Q. Extending Medicaid to Address Community Needs

Similar to waiver requests by other states, New York seeks additional flexibility in covering certain community based and social care services that help contain the spread of COVID-19. These additional flexibilities include extending Medicaid coverage to housing-related services, including temporary housing, housing application assistance, and transfer/moving expenses, in order to safely discharge homeless individuals or those without a safe and an appropriate discharge location. Additionally, New York seeks a waiver to extend Medicaid coverage to nutritional services, including healthy meals for families who may not have access to meals during the interrupted period of social distancing.

R. Additional Flexibilities

New York is seeking 1135 authority for the following other flexibilities that were not specifically mentioned in recent CMS guidance. Nonetheless, New York (as other states have) believe these requests constitute critical authorities to preserving resources and ensuring on-going access to health care items and services to respond to this public health crisis:

- Similar to Washington state, simplifying program administration by allowing for temporary state plan flexibilities, such as lifting benefit limits, cost sharing, applying targeted rate increases for certain providers, rather than requiring states go through the SPA submission and approval process, public notice rules (42 C.F.R. §§ 447.205 & 447.57);
- Allowing state to draw federal financing match for payments, such as hardship or supplemental payments, to stabilize and retain providers of Behavioral Health, Long Term Care settings (including home care workers), Health Homes, and Early Intervention providers who suffer extreme disruptions to their standard business model and/or revenue streams as a result of the public health emergency;
- Extending the implementation timeline for New York to implement an Electronic Visit Verification ("**EVV**") system by the length of the public health emergency, such that the length of the public health emergency extend the period of implementation beyond January 1, 2021 for all Medicaid-funded personal care services under the 21st Century Cures Act. Given the public health emergency, the State and providers may be delayed in their ability to implement EVV by the required implementation timeframe and such any delays beyond the current deadline should not result in penalties to the State's Federal Medical Assistance Percentage for delayed implementation;
- Permitting providers for individuals with intellectual and developmental disabilities, as authorized under New York's Home and Community Based Service ("**HCBS**") Waiver 0238.06.00, to implement retainer day payments for Day Habilitation and Prevocational Services, and potentially other HCBS services, such that these would be eligible for up to 30 consecutive days of retainer day payments.[3]
- Temporarily allowing non-emergency ambulance suppliers and non-enrolled Non-Emergency Medical Transportation ("**NEMT**") providers to provide NEMT services;
- Suspending replacement requirements for Durable Medical Equipment Prosthetics, Orthotics, and Supplies that are lost, destroyed, irreparably damaged, or otherwise rendered unusable, such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required for replacement;
- Allowing Federally Qualified Health Centers ("**FQHC**") and Rural Health Clinics ("**RHC**") providers to bill for their Prospective Payment System ("**PPS**") rate, or other permissible reimbursement, when providing services from alternative physical settings, such as a mobile clinic or temporary location, which will allow flexibility in site of clinics to promote appropriate infection control;
- Temporarily delaying, modifying or suspending CMS-certified facilities' onsite survey, re-certification and revisit surveys conducted by the State survey agency, and some enforcement actions, and/or allowing additional time for facilities to submit plans of correction, and waiving state performance standards and requirements for the current federal fiscal year or longer if the emergency extends beyond the federal fiscal year

[3] In discussions with the Division of Long-Term Supports and Services at CMS, New York was instructed to seek this flexibility under an 1135 Waiver request for these retainer payments, which are also being requested under an Appendix K submission to the applicable 1915(c) waiver.

(New York seeks to slightly modify the authority approval described in August 20, 2018 CMS Disaster Relief Inventory);

- Waiving timely filing requirements for billing that will allow providers getting correct coding and other structural pieces built into their systems and even payer ability to adjudicate (42 U.S.C. § 1396a(a)(54), and 42 U.S.C. §§ 1395cc(a)(1)(57), & (w), 42 CFR § 424.44).
- Removing the 13-day payment "floor" before clean Medicare claims can be processed for payment, as this removal will help expedite cash flow for providers in this critical time;
- Delaying the timeframe for submission of monthly T-MSIS reporting;
- Waiving certain regulatory equipment requirements, as further described in CMS Hospital Equipment Maintenance Requirements guidance issued in December 20, 2013 in order to maintain the health and safety of the hospitals' patients and providers (42 C.F.R. § 482.41(c)); and
- Waiving timeliness requirements related to triaging complaints and investigation of complaints in CMS-certified facilities unless it involves an immediate jeopardy or infection control; when investigating a complaint related to an immediate jeopardy or infection control, personal protection equipment requirement must be available for use by the surveyor/investigator.

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We thank you for your approval of waivers of federal Medicaid, Medicare, CHIP and HIPAA requirements necessary for New York to implement the above actions to respond to the COVID-19 pandemic. We also appreciate your partnership and consideration if and when the State identifies additional flexibility requests not included in this letter; such additional requests will be outlined in a subsequent written request.

Thank you for your flexibility and willingness to work with the State during these difficult times.

Very truly yours,

Howard A. Zucker, M.D., J.D.
Commissioner

cc: Calder Lynch
Sally Dreslin
Donna Frescatore
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