NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Health Benefits

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
DAVE RICHARD • Deputy Secretary, NC Medicaid

March 17, 2020

Charles Friedrich
CMCS| Medicaid and CHIP Operations Group (MCOG)
Office of the Regional Administrator
Atlanta Federal Center
61 Forsyth Street, SW, Suite 4T20
Atlanta, Georgia 30303-8909

Via email transmittal to Charles.Friedrich@cms.hhs.gov

Dear Mr. Friedrich,

On January 31, 2020, in anticipation of the effects of 2019 Novel Coronavirus (2019-nCoV), 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.

As authorized under Section 1135 of the Social Security Act, North Carolina is respectfully requesting waivers of certain federal Medicare, Medicaid, CHIP and HIPAA requirements to ensure that sufficient health care items and services are available to meet the needs of our state residents and providers. These waivers will give North Carolina the flexibility to implement changes, as needed, to address any urgent health care needs of our residents. Please note that North Carolina is implementing all of the blanket waivers announced by CMS on March 13, 2020 in Medicaid and CHIP, to the extent applicable. In addition, North Carolina expects its licensed providers will operate under all CMS blanket waivers announced by CMS on March 13, 2020. The purpose of this letter is to seek additional waivers for CMS approval. Because we are still analyzing and evaluating the HHS-authorized blanket waiver authorities, some of the additional waivers we request may be covered under your blanket waivers. Our intent is to utilize the HHS-authorized blanket waivers and we may modify this supplemental request to the extent that we identify items that are encompassed by the existing blanket waivers.

North Carolina is seeking to avail itself of already approved 1135 waivers as authorized under March 13, 2020 CMS Guidance and Secretary Azar's March 13, 2020 Declaration:

- **Waive the Critical Access Hospital (CAH) limit of beds to 25 and length of stay 96 hours.**
  North Carolina is requesting a blanket waiver for this authority;

- **Waive certain provider screening and enrollment requirements.**
  - Temporarily waiving payment of application fee to temporarily enroll a provider;
  - Temporarily waiving criminal background checks to temporarily enroll a provider;
  - Temporarily waiving site visits to temporarily enroll a provider;
  - Temporarily ceasing revalidation of providers who are enrolled with NC Medicaid or otherwise directly impacted by the emergency;
  - Temporarily waiving 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 enrolled with Medicare;
  - Temporarily suspending pending enforcement or termination action or denial of payment sanction to a specific provider;
  - 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,
  - Establishing a toll-free hotline for non-certified Part B suppliers, physicians and nonphysician practitioners to enroll and receive temporary Medicare billing privileges.

- **Waive certain hospital regulatory requirements**.
  - Allowing acute care hospitals to house acute care 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 acute care 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 acute care 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;
    - Waive the following requests for Medicare appeals in Fee for Service, MA 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 don't 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.

- **Waive certain Health Insurance Portability and Accountability Act (HIPAA) requirements.** North Carolina is requesting blanket waiver authority to temporarily suspend the application of sanctions and penalties arising from non-compliance with HIPAA requirements related to the following (as authorized in Secretary Azar's March 13, 2020 declaration):
    - Obtaining a patient's agreement to speak with family members or friends (as authorized in Secretary Azar's March 13, 2020 declaration);
    - Honoring a request to opt out of the facility directory (as authorized in Secretary Azar's March 13, 2020 declaration);
    - Distributing a notice (as authorized in Secretary Azar's March 13, 2020 declaration);
    - The patient's right to request privacy restrictions (as authorized in Secretary Azar's March 13, 2020 declaration);
    - The patient's right to request confidential communications (as authorized in Secretary Azar's March 13, 2020 declaration); and
    - Enabling the State to temporarily allow the use of non-HIPAA compliant telehealth technologies (North Carolina is seeking to approval of this additional HIPAA waiver request to the list of approved waivers).

- **Waive certain Emergency Medical Treatment and Labor Act (EMTALA) requirements.** North Carolina is requesting blanket waiver authority to 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).

North Carolina is also seeking 1135 waiver approval from certain requirements as described in the August 20, 2018, CMS Disaster Relief Inventory and as authorized under March 13, 2020 CMS Guidance:

- **Waive certain reporting, oversight and fair hearing requirements.** North Carolina is requesting blanket waiver authority for the following (as described in the August 20, 2018, CMS Disaster Relief Inventory):

- Adjusting performance deadlines and timetables for required reporting and oversight activities;
- Suspending pre-admission screening and annual resident review (PASRR) Level I and Level II Assessments while the federal and state emergencies are in effect;
- Modifying deadlines for CMS Outcome and Assessment Information Set (OASIS) and Minimum Data Set (MDS) assessments and transmission;
- Allow Medicare Administrative Contractors to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies;
- Temporarily delaying, modifying or suspending CMS-certified or tribal facilities' onsite survey, re-certification and revisit surveys conducted by the federal government or 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 (North Carolina seeks to slightly modify the authority approval described in August 20, 2018 CMS Disaster Relief Inventory);
- Temporarily suspending 2-week aide supervision requirement by a registered nurse for home health agencies;
- Temporarily suspending the requirement of supervision of hospice aides by a registered nurse every 14 days for hospice agencies; and,
- Allowing Medicaid/CHIP enrollees to have more than 90 days (eligibility or fee-for-service appeal) to request a state fair hearing.
- Modify the timeframe for managed care entities to resolve appeals under 42 C.F.R. §438.408(f)(1) before an enrollee may request a State fair hearing to zero days in accordance with the requirements specified below.
- Extend timelines for more than 120 days for managed care enrollees to request a State Fair Hearing

- **Waive certain benefit and authorization requirements.** (As described in March 13, 2020 CMS Guidance):
  - Waiving prior authorizations in Medicaid;
  - Extending minimum data set authorizations for nursing facility and Skilled Nursing Facility (SNF) residents;
  - Suspending the three-day hospitalization requirement prior to Medicare-covered admission to skilled nursing facilities;
  - Enabling certain beneficiaries who recently exhausted their SNF benefits to obtain renewed SNF coverage without first having to start a new benefit period; and,
  - Suspending replacement requirements for Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) 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.

We are seeking 1135 authority for the following flexibilities that were not articulated in recent CMS guidance and have not been previously approved in other states' 1135 waiver requests but are critical authorities to ensuring on-going access to health care items and services to respond to this public health crisis:

- Simplifying program administration by allowing for temporary state plan flexibilities, such as lifting benefit limits, cost sharing, applying targeted rate increases for certain provider types or specialties, rather than requiring states go through the SPA submission and approval process. State will memorialize the temporary State Plan changes in formal documentation submitted to CMS;
- Suspending SNF bed hold timelines for SNF residents that are temporarily moved home or who go into a hospital;
- Temporarily allowing non-emergency ambulance suppliers and non-enrolled NEMT providers to provide NEMT services;
- Enabling State to briefly shelter patients at non-certified/licensed facilities;
- Waiving timeliness requirements related to triaging complaints and investigation of complaints in CMS-certified facilities unless it involves immediate jeopardy complaints (cases that represent a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death or harm) and allegations of abuse and neglect or complaints alleging serious infection control concerns; when investigating a complaint related to an immediate jeopardy or infection control, personal protection equipment must be available for use by the surveyor/investigator;
- Allowing state to draw federal financing match (at regular FMAP rates) for payments, such as hardship or supplemental payments, to stabilize and retain providers of Behavioral Health/IDD, Long Term Care settings (including home care and community health workers), IHS Providers 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;
- Suspending required eligibility assessment for patients going from a SNF to home setting (or do assessment at sending entity; follow-up assessments or modifications can be done at a later date);
- Enabling hospitals that do not have either a hospital-based SNF or a swing bed unit to use their acute care beds to provide SNF level care;
- Allowing flexibility to cover 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; and,
- Allowing the authority to provide nutritional services including healthy meals for families who may not have access to meals during the interrupted period of social distancing.

North Carolina is also seeking waiver authority on behalf of our hospital providers for the following:

- Discharge Planning. 42 C.F.R. §482.43(a)(8), 485.642(a)(8) Hospitals can discharge patients who no longer need acute care based solely upon which post-acute providers can accept them without sharing the data requested by the regulators;
- Medicare Conditions of Participation (CoPs).
    - Physical Environment. 42 C.F.R. §482.41; A-0700 et seq;
        - Approve the use of technology and physical barriers that limit exposure and potential spread of the virus, such as use of video and audio resources

for limiting direct contact between physicians and other providers in the same clinical facility.
        - Permit basic evaluation, specimen collection, and treatment to occur in patient vehicles, assuming patient safety and comfort. As many facilities are standing up drive through specimen collection sites, we'd like to request that basic evaluation and treatment be allowed in patient vehicles in order to prevent potential spread of the virus to the facility.
    - Patient Rights. 42 C.F.R. §482.13. Waive enforcement of patient rights related to personal privacy, confidentiality (see HIPAA request above), orders for seclusion, and patient visitation rights.
    - Sterile Compounding. 42 C.F.R. §482.25(b)(1) and USP 797 Face masks can be removed and retained in the compounding area to be re-donned and reused during the same work shift only. This will conserve scarce face mask supplies which will help with the impending shortage of personal protective equipment.
    - Verbal Orders §482.24, A-0407, A-0454, A-0457 Verbal orders may be used more than 'infrequently' (read-back verification is done) and authentication may occur later than 48 hours. This 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 ICU patients whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs may be reported later than close of business 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 whose privileges will expire and new physicians to practice before full medical staff/governing body review and approval, provided that such review and approval would be secured at the next practical opportunity. This will keep clinicians on the front line and allow hospitals and health systems to prioritize patient care needs during the emergency.
    - Medical Records Timing**.** 42 C.F.R. §482.24; A-0469 Medical records can be fully completed later than 30 days following discharge but must be completed no later than 60 days following the termination of the emergency period. This flexibility will allow clinicians to focus on the care needs at hand and complete full documentation later.
- Physician referral. Waive sanctions under section 1877(g) of the Social Security Act (relating to limitations on physician referral). This will allow hospitals to compensate physicians for unexpected or burdensome work demands (e.g., hazard pay), encourage multi-state systems to recruit additional practitioners from out-of-state, and eliminate a barrier to efficient placement of patients in care settings.
- Telehealth. 42 C.F.R. §410.78(b).
    - Consistent with the authority granted the Secretary under the *Coronavirus Preparedness and Response Supplemental Appropriations Act*, eliminate Medicare restrictions on licensing for telehealth and geographic restrictions on originating sites. Allow billing using CPT codes 99444 and 98969 for both new and established patients. Ask the HHS OIG to confirm that telemedicine

screenings without co-pays and deductibles do not violate the CMP law or anti-kickback statute.
    - Eliminate the requirement that in order to bill for a telehealth service a provider or a provider in their practice or in the health system 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.
- Home Health. 42 C.F.R. § 484.55(a); Home health agencies can perform certifications, initial assessments and determine patients' homebound status remotely or by record review.
- Delivery of Services in Alternate Clinic Locations. Waiver/flexibility to allow Federally Qualified Health Centers (FQHC),Rural Health Clinics (RHC) and IHS/Tribal 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. This will allow flexibility in site of clinics to promote appropriate infection control.
- Flexibility for Teaching Hospitals**.** Allow flexibility in how the teaching physician is present with the patient and resident including real time-audio video or access through a window.
- Flexibility in Patient Self Determination Act Requirements. 42 CFR 489.102
- Timely Filing Requirements for Billing. 42 U.S.C. 1396a(a)(54), and 42 U.S.C. 1395cc(a)(1)(57), (w), 42 CFR 424.44 Waiver of timely filing requirements that will allow providers getting correct coding and other structural pieces built into their systems and even payer ability to adjudicate.
- Flexibility in Equipment Requirements. Waiver of certain equipment requirements 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.
- Flexibility for Concurrent Respiratory Therapy. Allow providers to access Medicare reimbursement for concurrent respiratory therapy (i.e., when a respiratory professional treats more than one patient at a time) in order to manage large volumes of patients requiring treatment.

We thank you for your approval of waivers of federal Medicaid, Medicare, CHIP and HIPAA requirements necessary for North Carolina 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.

Sincerely,

DocuSigned by:
Dave Richard
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Dave Richard

Cc: Jackie Glaze, CMCS
Shantrina Roberts, CMCS
Melanie Bush, NC Medicaid
Betty J. Staton, NC Medicaid