



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

August 13, 2020

Davida R. Kimble
Acting Deputy Director
Division of Medicaid Field Operations South
Centers for Medicare and Medicaid Services
Region IV
Atlanta Federal Center
61 Forsyth St SW Suite 4T20
Atlanta, GA 30303-8909

Via email transmittal to Davida.Kimble@cms.hhs.gov

Dear Ms. Kimble:

The North Carolina Department of Health and Human Services (“DHHS”) writes to request approval for certain waivers under section 1135 of the Social Security Act (the “Act”) as related to the Novel Coronavirus Disease (“COVID-19”) pandemic. As you know, the Secretary of Health & Human Services (the “Secretary”) invoked his authority under section 1135 on March 13, 2020 (the “Secretary’s 1135 Waiver”) in light of the President’s declaration of a national emergency earlier that day, and the Secretary’s prior declaration of a nationwide health emergency on January 31, 2020. The Secretary has authorized a waiver or modification of certain federal requirements pertaining to Medicare, Medicaid, and the Children’s Health Insurance Program (“CHIP”) as necessary to ensure that:

- “[S]ufficient health care items and services are available to meet the needs” of beneficiaries in these programs; and
- Providers may be reimbursed for, and protected against sanctions in connection with, services furnished in good faith during the emergency, notwithstanding their inability to comply certain program requirements as a result of the emergency situation created by COVID-19.¹

Subsequently, CMS [issued](#) a series of blanket waivers beginning on March 13, 2020, followed by periodic updates. It also [approved](#) on March 23, 2020 a series of waivers requested by DHHS. DHHS and impacted healthcare providers and suppliers are currently exercising flexibilities granted in these waivers.

¹ Waiver or Modification of Requirements Under Section 1135 of the Social Security Act, Public Health Emergency, U.S. Dep’t of Health & Human Services (“HHS”) (Mar. 13, 2020), <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>.

NC MEDICAID

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH BENEFITS

LOCATION: 1985 Umstead Drive, Kirby Building, Raleigh NC 27603
MAILING ADDRESS: 2501 Mail Service Center, Raleigh NC 27699-2501
www.ncdhhs.gov • TEL: 919-855-4100 • FAX: 919-733-6608

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

This letter serves to request that CMS approve certain additional blanket waivers on either a state-specific or nationwide basis. These are described below.

Request for Additional Flexibilities under Section 1135

Medicaid-Funded Home and Community-Based Services (“HCBS”)

- Conflict of Interest Requirements for HCBS. Permit the state to temporarily authorize reimbursement for home and community-based services (HCBS) provided by an entity that also provides case management services and/or is responsible for the development of the person-centered service plan in circumstances beyond the limited authority provided under regulations. This waiver applies to provisions at 42 C.F.R. §441.301(c)(1)(vi) for 1915(c) HCBS waivers. *CMS has approved a similar waiver in other states under section 1135(b)(1)(B) of the Act (waiver of “program participation” requirements).*
- Modify the deadlines for initial and annual level of care determinations required for section 1915(c) HCBS waiver programs. This waiver applies to provisions at 42 C.F.R. § 441.302(c)(1) and (c)(2), respectively. This would eliminate the requirements that level of care determinations be completed before the start of services, allow annual level of care determinations that exceed the 12-month authorization period to remain in place and services to continue until the assessment can occur, and allow reassessments to be postponed for up to one year. *CMS has approved a similar waiver in other states under section 1135(b)(5) of the Act (waiver of “deadlines and timetables”).*

Administrative Flexibilities Regarding Medicaid Procedures

- Extend the two-year timeframe during which state Medicaid agencies may adjust their claims for federal financial participation, as described in 45 C.F.R. § 95.7. This waiver would ensure that agencies can focus on the exigencies of the present crisis. Alternatively, CMS could issue guidance clarifying that COVID-related delays will satisfy the “good cause” exemption to the two-year timeframe, as described in 45 C.F.R. § 95.19(d). *This waiver is available pursuant to section 1135(b)(5) of the Act (waiver of “deadlines and timetables”).*

Prior Authorization under the State Medicaid Plan

- With respect to services approved to be provided on or after March 1, 2020, permit these services to continue to be provided without a requirement for a new or renewed prior authorization, through the termination of the public health emergency. *CMS has approved a similar waiver in other states under section 1135(b)(1)(C) of the Act (waiver of “pre-approval requirements”).*

Intermediate Care Facilities (“ICFs”)

- Modify the requirements at 42 C.F.R. §§ 483.470(l) and 483.460(c)(5)(ii) to allow reasonable alternative protective measures when personal protective equipment is unavailable due to

supply chain disruption. For example, regulations require staff to wear a paper gown when disposing of certain hazardous drugs. If paper gowns become unavailable, allow staff to wear washable gowns when disposing of hazardous medications. *This flexibility may already have been authorized as part of CMS's guidance on ICF infection control.² Please confirm if so. If not, this waiver is available pursuant to section 1135(b)(1)(A) of the Act (waiver of "conditions of participation").*

- Permit the temporary suspension of the requirement for specialized services, as described at 42 C.F.R. § 483.440(a)(1), for facilities that receive a bundled payment for all services or if necessary to minimize unnecessary person-to-person contact that could potentially spread COVID-19. With regard to the latter, for example, the State could suspend the requirement on a limited basis (i.e., in targeted geographies or facilities) that ICFs deliver physical therapy to program participants if the State determines that such activities may result in the spread of the virus to residents due to high transmission rates in the area. Facilities in North Carolina would be permitted to suspend specialized services only to the extent permitted by State policy directive that the State is availing itself of this flexibility once obtained. *This waiver, which builds on CMS's existing blanket waiver regarding ICF active treatment, is available pursuant to section 1135(b)(1)(A) of the Act (waiver of "conditions of participation").*
- Permit the temporary suspension of the requirements at 42 C.F.R. § 483.420(c) for ICFs to promote visits from outside individuals, such as a resident's friends and family members under state directive. This waiver would help to minimize the risk of infection for residents and staff. Facilities in North Carolina would be permitted to suspend visitation only to the extent that doing so is consistent with State policy directive that the State is availing itself of this flexibility once obtained. *This flexibility may already be available under existing rules and CMS's guidance on ICF infection control. Please confirm if so. If not, this waiver is available pursuant to section 1135(b)(1)(A) of the Act (waiver of "conditions of participation")*
- Relax the "physical environment" conditions of participation at 42 C.F.R. § 483.470 so that ICFs have additional flexibility to implement social distancing and isolation measures. ICFs could, for example, house clients of grossly different ages, developmental levels, and social needs to be housed together as necessary to accommodate COVID-related relocations and isolation measures. *This waiver, which builds on CMS's existing blanket waivers regarding ICF "physical environment," is available pursuant to section 1135(b)(1)(A) of the Act (waiver of "conditions of participation").*

Home Health (State Plan Only)

- With respect to the home health aide training requirements at 42 C.F.R. § 484.80, permit all "in-service" and "in-person" trainings to be conducted remotely, or otherwise suspend these requirements and permit any recertifications to be conducted through online competency evaluations. *This waiver, which builds on CMS's existing blanket waiver regarding home health*

² See CMS, Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) and Psychiatric Residential Treatment Facilities (PRTFs), QSO-20-23-ICF/IID & PRTF, at 8 (Mar. 30, 2020), <https://www.cms.gov/files/document/qso-20-23-icf-iid-prtf.pdf>.

aide training, is available pursuant to section 1135(b)(1)(A) of the Act (waiver of “conditions of participation”).

- Modify the deadline for the face-to-face encounter required for Medicaid-covered Home Health services, as described in 42 CFR §440.70(f)(1) and 440.70(f)(2). This would eliminate the requirement that face-to-face encounters be completed before the start of services and allow them to be completed up to 12 months from the start of service. *CMS has approved a similar waiver in other states under 1135(b)(5) of the Act (waiver of “deadlines and timetables”).*

Hospice

- Extend the five-day timeframe for hospice providers to submit Notices of Election and Notices of Termination/Revocation, as described at 42 C.F.R. §§ 418.24(a), 418.26(e), and 418.28(d). *This waiver is available pursuant to section 1135(b)(5) of the Act (waiver of “deadlines and timetables”).*
- Extend the deadlines for collection and submission of the Hospice Item Set until the conclusion of the nationwide public health emergency. *This waiver is available pursuant to section 1135(b)(5) of the Act (waiver of “deadlines and timetables”).*

Programs of All-Inclusive Care for the Elderly (“PACE”) Organizations

- Extend the time periods for conducting semi-annual reassessments, as described in 42 C.F.R. § 460.104(c). *This waiver is available pursuant to section 1135(b)(1)(B) of the Act (waiver of “program participation” requirements) and also section 1135(b)(5).*

Pharmacy

- Provide any necessary flexibilities so that pharmacies can be used as COVID-19 testing sites reimbursable under Medicare and Medicaid, including the use of parking lots, in-car testing, and drive-throughs to minimize interpersonal contact. *This flexibility may already have been authorized under CMS’s interim final rules and existing CLIA guidance. Please confirm if so. If not, this waiver is available pursuant to section 1135(b)(1)(A) of the Act (waiver of “conditions of participation”) and also section 1135(b)(1)(B) (waiver of “program participation” requirements).*

The contact person for this waiver request is:

Dave Richard
Deputy Secretary
Department of Health and Human Services, Division of Health Benefits
1985 Umstead Drive
2501 Mail Service Center
Raleigh, NC 27699-2501
dave.richard@dhhs.nc.gov

The expected duration of the waiver is March 1, 2020 (the effective date of the Secretary’s 1135 Waiver) until the COVID-19 national public health emergency terminates.

Thank you for considering these requests so that North Carolina can effectively manage this difficult and unprecedented epidemic.

Sincerely,

DocuSigned by:
Dave Richard
11395D232A054A2...

Dave Richard
Deputy Secretary, NC Medicaid