NATIONAL ASSOCIATION OF Community Health Centers

MEMORANDUM

TO: PCAs
FROM: Public Policy and Research Division
DATE: March 19, 2020
RE: **Section 1135 Waivers: Elements Necessary for FQHCs**

QUICK GUIDE

Page 1 Overview
Page 2 FQHC Specific Potential 1135 Waiver Provisions
Page 4 Non-FQHC Specific Potential 1135 Waiver Provisions
Page 5 Section 1135 Waivers: In Detail
Page 6 Guidance and Resource

OVERVIEW

Section 1135 waivers enable states to meet health care needs during times of disaster and crisis. Section 1135 waivers require *both* a declaration of national emergency or disaster by the president under the National Emergencies Act *or* the Stafford Act *and* a public health emergency determination by the HHS secretary under Section 319 of the Public Health Service Act. Section 1135 of the Social Security Act gives the HHS Secretary the authority to temporarily waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) requirements for ensuring that:

- "sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods" and
- "providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse)."

Washington state just submitted a robust 1135 waiver request that in summary that includes CMS-issued blanket waivers and specific waivers to address *(see detailed list of key elements further down):*

- *Workforce* (e.g., licensure and services across state lines)
- *Facilities / Alternative Site Locations* (e.g., reimbursement for services from alternative physical settings like mobile clinics)
- *Telehealth Delivery and Payment* (e.g., distant site reimbursement and telephone-only services)
- *Medicaid / CHIP Flexibility* (e.g., eligibility and enrollment flexibility, waiver of face-to-face requirements, and cessation of provider renewal requirements)

The following is a detailed list of waiver elements that are key to helping FQHCs address the health care needs of patients and communities during the COVID-19 public health emergency. This list is largely based on the waivers requested by the state of Washington. The selected provisions may crossover into different issue areas and some language from Washington has been edited by NACHC staff. Local policies will determine if and how these provisions are applicable to FQHCs in other states, and other equally important waiver requests are listed in a separate section below.

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POTENTIAL 1135 WAIVER PROVISIONS – FQHC SPECIFIC

Site-Related Provisions

- **Delivery of Services in Alternate Clinic Locations.** Waiver/flexibility to allow 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. This will allow flexibility in site of clinics to promote appropriate infection control.
- **Permit distant site (provider) services via telehealth** to be rendered in a rural health clinic (RHC). Currently Medicare prohibits distant site telehealth to be rendered by a provider in a RHC. This limitation is not by regulation, but rather, sub-regulatory guidance. RHCs have very limited resources and providers. For the RHCs' protection and sustainability the state requests to have the telehealth prohibition lifted to allow RHC providers to render telehealth treatment in the RHC. This limitation is not contained in the RHC regulations at 42 CFR 491; rather it is contained in sub-regulatory guidance that first appeared in 2013.
- **Allow capacity funding for providers**. This may include grants, Medicaid financing, or other funding available to be used for purchase of equipment and supplies as necessary for providers and patients (e.g., personal protective equipment and cleaning supplies, laptops, additional cell-phones or additional cell-phone plan minutes for clients so they are free to use the phone for services).

Telehealth Provisions

- 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 must have billed that Medicaid or Medicare enrollee for a service within the previous three years.
- Allow **E&M codes** to be billed via telehealth or telephonic services even for first time patients.
- Allow for **reimbursement for telephone visits at the same rate as telehealth video visits.** For many cases the video aspect does not add value to the patient interaction – it's the information relayed to the patient that matters. See CPT codes 99441, 99442, 99443; HCPCS G2012, G0071. In addition, consistent with our request above for the **codes to be opened for new patients in addition to the established patients**, which these codes currently only apply. While states may have the authority to implement this policy under Medicaid, this waiver is necessary under Medicare.
- Direct OTP providers to utilize telehealth options for those in need without requiring an in person medical evaluation in cases where the person is compliant with dosing or in cases where the medication of choice is **Bupenorphine.**

Medicaid/CHIP Provisions

- Allow **self-attestation** for all eligibility criteria (excluding citizenship and immigration status) on a case-by-case basis for Medicaid and CHIP eligible individuals subject to a disaster when documentation is not available as outlined at 42 CFR 435.952(c)(3); 42 CFR 457.380.
- Allow **presumptive Medicaid eligibility** for the Aged, Blind, and Disabled population.

- Extend redetermination timelines for current Medicaid enrollees in the state to maintain continuity of coverage as permissible under 42 CFR 435.912(e).
- Waive requirement that State must submit and receive CMS approval of a Title XIX or Title XX state plan amendment in order to temporarily waive any patient cost-sharing associated with COVID-9 screening, testing, and treatment.
- Due to the extraordinary nature of this emergency, we request a waiver of the requirement for actuarially sound Medicaid managed care rates, under 42 C.F.R. Part 438, for calendar years 2020 and 2021. This waiver would apply to all Medicaid managed care programs and contracts. An important element of this request is allowing, particularly smaller and more vulnerable providers like behavioral health providers, ability to be paid if they have not been able to perform services due to quarantine. The state understands that this may require an 1115 waiver, in which in light of the emergency, the state requests that it would not have to meet transparency requirements.
- Comparability – Section 1902(a)(10)(B). To enable the State to deliver different services and service delivery methods to affected beneficiaries than are otherwise available to non-affected beneficiaries.
- Annual Redeterminations of Eligibility – Sections 1902(a)(4) and 1902(a)(19). To permit delay of otherwise required redeterminations for the State's XIX program.
- Amount, Duration, and Scope – Section 1902(a)(10)(B). To the extent necessary to enable the state to offer different benefits to affected beneficiaries.
- We request enhanced eligibility levels for those uninsured under the crisis period who may be above the 135% to 200% FPL and lift the 5-year bar period.
- Broadly waive any other face-to-face requirement.
- Temporarily delaying, modifying or suspending CMS-certified facilities' onsite survey, recertification 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.
- Temporarily cease the revalidation of and waive provider renewal requirements during this state of emergency.
- Temporarily waive requirements that out-of-state providers be licensed in the State when they are licensed by another state Medicaid agency or by Medicare.
- Allow facilities to provide services in alternative settings, such as a temporary shelter or through mobile-units. This may include potential relief from Drug Enforcement Administration (DEA) requirements around medications.
- Waive requirements for site visits to enroll a provider
- Suspend Medicaid fee-for-service prior authorization requirements
- Permit payment for home and community-based services (HCBS) rendered by family caregivers or legally responsible individuals;
- Expand the provision of home delivered meals to all eligible populations;
- Provide temporary housing, not to exceed six months, if a beneficiary is homeless or is at imminent risk of homelessness and has tested positive for COVID-19;
- Suspend existing cost sharing requirements for all members

POTENTIAL 1135 WAIVER PROVISIONS – NON-FQHC SPECIFIC

Blanket Waivers from CMS

- State is implementing all of the **blanket waivers** announced by CMS on March 13, 2020 in Medicaid and CHIP, to the extent applicable; (2) State licensed providers authority will operate under all CMS blanket waivers announced by CMS on March 13; (3) State is seeking additional blanket waivers [], under which "all CMS licensed providers will operate upon CMS approval." (See the Washington waiver request.)
- **EMTALA**: Emergency Medical Treatment and Active Labor Act**.** Suspend enforcement of section 1867 of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals to screen or triage patients at a location offsite from the hospital's campus and transfer patients according to protocols that account for COVID-19 status, not just according to existing transfer requirements.

HIPAA Regulations Waiver Requests

- **HIPAA Privacy**. Pursuant to Section 1135(b)(7) of the Social Security Act, waive sanctions and penalties arising from noncompliance with certain HIPAA privacy regulations, including : 1) obtaining a patient's agreement to speak with family or friends or honoring a patient's request to opt out of the facility directory; 2) distributing a notice of privacy practices; or 3) the patient's right to request confidential communications.
- **HIPAA Security Requirements**. 45 C.F.R. 164.312(e)(1) – Transmission Security; Waive the security requirements for video communication in a telehealth visit. While CMS has lifted many of the patient site requirements to allow telehealth in the home as well as nonrural areas, many facilities are not prepared with secure platforms that they own and control which are also accessible to the patient. The request is to allow providers to use readily available platforms like Facetime, WhatsApp, Skype, etc. to facilitate the telehealth visit with the patient at home.
- **Code sets.** Request to waive HIPAA EDI code set requirements 45 CFR Part 162.1002. This would allow the State the 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 the State to track and set rates for services specific to COVID-19.

Medicaid and Medicare Hospital Conditions of Participation

- 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 **treatment to occur in patient vehicles**, assuming patient safety and comfort. Many facilities are standing up drive through specimen collection sites, we'd like to request 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 t personal privacy, confidentiality (see HIPAA request below), orders for seclusion, an patient visitation rights. This is necessary because hospitals may be required t undertake public emergency responses that make compliance with those CoP requirements impossible.
- **Sterile Compounding.** 42 C.F.R. §482.25(b)(1) and USP 797 Face masks can be remove 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 medications.

- **Medical Staff.** 42 C.F.R. §482.22(a); A-0341 So that physicians whose privileges will expire and new physicians can practice before full medical staff/governing body review and approval. 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. This flexibility will allow clinicians to focus on the care needs at hand and deal with paperwork later.

SECTION 1135 WAIVERS: IN DETAIL

Scope, Purpose, and Duration

As explained by CMS, the scope, purpose, and duration of 1135 waivers are as follows:

Scope: Federal Requirements only, not state licensure or conditions of participation.

Purpose: Allow reimbursement during an emergency or disaster even if providers can't comply with certain requirements that would under normal circumstances bar Medicare, Medicaid or CHIP payment

Duration: End no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period. Waivers for EMTALA (for public health emergencies that do *not* involve a pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a *hospital* disaster protocol.

Considerations for Providers and States

CMS continues to build upon its guidance learned through experience on how 1135 waivers can help states address the emergent needs of providers and the public in times of crisis. CMS advises providers and states to consider the following when developing 1135 waiver proposals:

- Are CMS regulations impeding your ability to respond to or recover from a disaster?
- What is the scope and severity of the event, with specific focus on health care infrastructure?
- Are there unmet needs for health care providers?
- Can these unmet needs be resolved within our current regulatory authority?

Waiver Input from Healthcare Providers

As CMS explains, in determining whether to approve an 1135 waiver, the HHS Assistant Secretary for Preparedness and Response (ASPR) considers "requests from Governor's offices, feedback from individual healthcare providers and associations, requests to regional or field offices for assistance, and information obtained from the Secretary's Operation Center." As such, **input from PCAs is critical to ensuring that 1135 waivers will assist FQHC providers in their response to declared disasters.**

It is also important for PCAs to keep in mind that **CMS considers public health emergencies due to diseases or viruses more diffuse and dispersed events.** As such, the justifications for an 1135 waiver related to such **outbreaks must consider the inherent variation in responses needed for different geographic areas.** In terms of process for gathering input on needed relief, CMS expects that most providers and associations will turn first to their CMS Regional Office (RO). Thus, PCAs are encouraged to coordinate with their CMS RO on seeking 1135 assistance.

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GUIDANCE AND RESOURCES

NACHC: Novel Coronavirus (COVID-19) Information and Resources for Community Health Centers

CMS:

CMS Disaster Response Toolkit
CMS 1135 Waivers Website, including:

- 1135 Waivers At A Glance (PDF)
- Requesting an 1135 Waiver 101 (PDF)
- 1135 Waivers Authority (PDF)
- Information to Provide for an 1135 Waiver Request (PDF)
- PHE Questions and Answers (PDF)

HRSA: Emergency Preparedness and Recovery Resources for Health Centers

Other:

How Can Medicaid Enhance State Capacity to Respond to COVID-19?
Published: Mar 17, 2020, KFF

COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies
Published 3/12/20, Updated 3/18/20, CMS (Check back often for updates)

Medicaid and CHIP Coverage Learning Collaborative Inventory of Medicaid and CHIP Flexibilities and Authorities in the Event of a Disaster
Published 2018, CMS

Section 1135 Waiver Examples

Arizona 1135 Waiver
Florida State 1135 Waiver (Approved by CMS)
Washington State 1135 Waiver

PCAs are strongly encouraged to closely track, identify, and help state authorities address local FQHCs needs to be addressed in 1135 and other types of waiver submissions. **Check CMS and HRSA websites frequently for updated guidance as this situation unfolds. Contact state@nachc.org to receive further assistance.**