DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

March 27, 2020

Stephen M. Groff
Director
Division of Medicaid and Medical Assistance
P.O. Box 906
New Castle, Delaware 19720-0906

Re: Section 1135 Flexibilities Requested in March 24, 2020 Communication

Dear Mr. Groff:

On March 13, 2020, the President of the United States issued a proclamation that the COVID-19 outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 *et seq*.), and consistent with section 1135 of the Social Security Act (Act). On March 13, 2020, pursuant to section 1135(b) of the Act, the Secretary of the United States Department of Health and Human Services invoked his authority to waive or modify certain requirements of titles XVIII, XIX, and XXI of the Act as a result of the consequences of the COVID-19 pandemic, to the extent necessary, as determined by the Centers for Medicare & Medicaid Services (CMS), to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the respective programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of such requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse. This authority took effect as of 6PM Eastern Standard Time on March 15, 2020, with a retroactive effective date of March 1, 2020. The emergency period will terminate, and section 1135 waivers will no longer be available, upon termination of the public health emergency, including any extensions.

Your communication to CMS on March 24, 2020, detai1ed a number of federal Medicaid and Medicare requirements that pose issues or challenges for the health care delivery system in all counties in Delaware and requested a waiver or modification of those requirements. Attached, please find a response to your requests for waivers or modifications, pursuant to section 1135 of the Social Security Act, to address the challenges posed by COVID-19. This approval addresses those requests related to Medicaid.

To streamline the section 1135 waiver request and approval process, CMS has issued a number of blanket waivers for many Medicare provisions, which primarily affect requirements for individual facilities, such as hospitals, long term care facilities, home health agencies, and so on. Waiver or modification of these provisions does not require individualized approval, and, therefore, these authorities are not addressed in this letter. Please refer to the current blanket waiver issued by CMS that can be found at https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf.

CMS continues to work on the additional waiver or modification requests that are not currently reflected in the attached approval. For those waiver or modification requests that require approval under authority other than section 1135, such as under applicable regulations, through an amendment to the state plan, or through a section 1115 demonstration, my staff will continue to work with your team to review and make determinations regarding approval as quickly as possible.

Please contact Jackie Glaze, Acting Director, Medicaid and CHIP Operations Group, at (404) 387-0121 or by email at Jackie.Glaze@cms.hhs.gov if you have any questions or need additional information. We appreciate the efforts of you and your staff in responding to the needs of the residents of the State of Delaware and the health care community.

Sincerely,

Calder Lynch
Deputy Administrator and Director

STATE OF DELAWARE
APPROVAL OF FEDERAL SECTION 1135 WAIVER REQUESTS

CMS Response: March 27, 2020

Temporarily suspend Medicaid fee-for-service prior authorization requirements. Section 1135(b)(1)(C) allows for a waiver or modification of pre-approval requirements, including prior authorization processes required under the State Plan for particular benefits.

Prior authorization and medical necessity processes in fee-for-service delivery systems are established, defined and administered at state/territory discretion and may vary depending on the benefit. See 42 C.F.R. §440.230(d). The State of Delaware may have indicated in its approved state plan specific requirements about prior authorization processes for benefits administered through the fee-for-service delivery system. We interpret prior authorization requirements to be a type of pre-approval requirement for which waiver and modification authority under section 1135(b)(1)(C) of the Act is available.

Extend pre-existing authorizations for which a beneficiary has previously received prior authorization through the end of the public health emergency.

If prior authorization processes are outlined in Delaware's state plan for particular benefits, CMS is using the flexibilities afforded under section 1135(b)(1)(C) of the Act that allow for waiver or modification of pre-approval requirements to permit services approved to be provided on or after March 1, 2020, to continue to be provided without a requirement for a new or renewed prior authorization, through the termination of the public health emergency, including any extensions (up to the last day of the emergency period under section 1135(e) of the Act), for beneficiaries with a permanent residence in the geographic area of the public health emergency declared by the Secretary.

Suspend Pre-Admission Screening and Annual Resident Review (PASRR) Level I and Level II Assessments for 30 days

Section 1919(e)(7) of the Act allows Level I and Level II assessments to be waived for 30 days. All new admissions can be treated like exempted hospital discharges. After 30 days, new admissions with mental illness (MI) or intellectual disability (ID) should receive a Resident Review as soon as resources become available.

Additionally, please note that per 42 C.F.R. §483.106(b)(4), new preadmission Level I and Level II screens are not required for residents who are being transferred between nursing facilities (NF). If the NF is not certain whether a Level I had been conducted at the resident's evacuating facility, a Level I can be conducted by the admitting facility during the first few days of admission as part of intake and transfers with positive Level I screens would require a Resident Review.

The 7-9-day timeframe for Level II completion is an annual average for all preadmission screens, not individual assessments, and only applies to the preadmission screens (42 C.F.R. §483.112(c)). There is not a set timeframe for when a Resident Review must be completed, but it should be conducted as resources become available.

State Fair Hearing Requests and Appeal Timelines

Delaware requested flexibility to temporarily delay scheduling of Medicaid fair hearings and issuing fair hearings decisions during the emergency period. CMS approves a waiver under section 1135 that allows enrollees to have more than 90 days, up to an additional 120 days for an eligibility or fee for service appeal to request a fair hearing. The timeframes in 42 C.F.R. §431.221(d) provides that states can choose a reasonable timeframe for individuals to request a fair hearing not to exceed 90 days for eligibility or fee-for-service issues.

CMS cannot waive parts of the Medicaid managed care regulations at 42 C.F.R. Part 438, Subpart F related to appeals of adverse benefit determinations which occur before Fair Hearings for managed care enrollees or parts of 42 C.F.R. Part 431, Subpart E. However, CMS is able to modify the federal timeframes associated with appeals and fair hearings. Therefore, CMS approves the following through the end of the public health emergency:

- Modification of 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 no less than one day in accordance with the requirements specified below; this allows managed care enrollees to proceed almost immediately to a state fair hearing without having a managed care plan resolve the appeal first by permitting the state to modify the timeline for managed care plans to resolve appeals to one day so the impacted appeals satisfy the exhaustion requirements.

The requirements of 42 C.F.R. §438.408(f)(1) establish that an enrollee may request a State fair hearing only after receiving a notice that the Managed Care Organization (MCO), Prepaid Inpatient Health Plan (PIHP) or Prepaid Ambulatory Health Plan (PAHP) is upholding the adverse benefit determination but also permits, at 42 C.F.R. §438.408(c)(3) and (f)(l)(i) that an enrollee's appeal may be deemed denied and the appeal process of the managed care plan exhausted (such that the State fair hearing may be requested) if the managed care plan fails to meet the timing and notice requirements of 42 C.F.R. §438.408. Section 1135 of the Act allows CMS to authorize a modification to the timeframes for required activities under section 1135(b)(5) of the Act. CMS authorizes the state to modify the time line for managed care plans to resolve appeals to no less than one day. If the state uses this authority, it would mean that all appeals filed between March 1, 2020 and the end of the public health emergency are deemed to satisfy the exhaustion requirement in 42 C.F.R. §438.408(f)(1) after one day (or more if that is the timeline elected by the state) and allow enrollees to file an appeal to the state fair hearing level.

- Modification of the timeframe under 42 C.F.R. §438.408(f)(2) for enrollees to exercise their appeal rights to allow an additional 120 days to request a fair hearing when the initial 120th day deadline for an enrollee occurred during the period of this section 1135 waiver.

In addition, CMS approves a modification of the timeframe, under 42 C.F.R. §438.408(f)(2), for managed care enrollees to exercise their appeal rights. Specifically, any managed care enrollees for whom the 120-day deadline described in 42 C.F.R. §438.408(f)(2) would have occurred between March 1, 2020 through the end of the public health emergency, are allowed up to an additional 120 days to request a State Fair Hearing.

Provider Enrollment

Delaware currently has the authority to rely upon provider screening that is performed by other State Medicaid Agencies (SMAs) and/or Medicare. As a result, Delaware is authorized to provisionally, temporarily enroll providers who are enrolled with another SMA or Medicare for the duration of the public health emergency.

Under current CMS policy, as explained in the Medicaid Provider Enrollment Compendium (7/24/18), at pg. 42, https://www.medicaid.gov/affordable-care-act/downloads/program-integrity/mpec-7242018.pdf, Delaware may reimburse otherwise payable claims from out-of-state providers not enrolled in the Delaware Medicaid program if the following criteria are met:

1. The item or service is furnished by an institutional provider, individual practitioner, or pharmacy at an out-of-state/territory practice location– i.e., located outside the geographical boundaries of the reimbursing state/territory's Medicaid plan,
2. The National Provider Identifier (NPI) of the furnishing provider is represented on the claim,
3. The furnishing provider is enrolled and in an "approved" status in Medicare or in another state/territory's Medicaid plan,
4. The claim represents services furnished, and;
5. The claim represents either:
    a. A single instance of care furnished over a 180-day period, or
    b. Multiple instances of care furnished to a single participant, over a 180-day period

For claims for services provided to Medicaid participants enrolled with Delaware Medicaid program, CMS will waive the fifth criterion listed above under section 1135(b)(1) of the Act. Therefore, for the duration of the public health emergency, Delaware may reimburse out-of-state providers for multiple instances of care to multiple participants, so long as the other criteria listed above are met.

If a certified provider is enrolled in Medicare or with a state Medicaid program other than

Delaware, Delaware may provisionally, temporarily enroll the out-of-state provider for the duration of the public health emergency in order to accommodate participants who were displaced by the emergency.

With respect to providers not already enrolled with another SMA or Medicare, CMS will waive the following screening requirements under 1135(b)(1) and (b)(2) of the Act, so the state may provisionally, temporarily enroll the providers for the duration of the public health emergency:

1. Payment of the application fee - 42 C.F.R. §455.460
2. Criminal background checks associated with Fingerprint-based Criminal Background Checks - 42 C.F.R. §455.434
3. Site visits - 42 C.F.R. §455.432
4. In-state/territory licensure requirements - 42 C.F.R. §455.412

CMS is granting this waiver authority to allow Delaware to enroll providers who are not currently enrolled with another SMA or Medicare so long as the state meets the following minimum requirements:

1. Must collect minimum data requirements in order to file and process claims, including, but not limited to NPI.
2. Must collect Social Security Number, Employer Identification Number, and Taxpayer Identification Number (SSN/EIN/TIN), as applicable, in order to perform the following screening requirements:
    a. OIG exclusion list
    b. State licensure – provider must be licensed, and legally authorized to practice or deliver the services for which they file claims, in at least one state/territory
3. Delaware must also:
    a. Issue no new temporary provisional enrollments after the date that the emergency designation is lifted,
    b. Cease payment to providers who are temporarily enrolled within six months from the termination of the public health emergency, including any extensions, unless a provider has submitted an application that meets all requirements for Medicaid participation and that application was subsequently reviewed and approved by Delaware before the end of the six month period after the termination of the public health emergency, including any extensions, and
    c. Allow a retroactive effective date for provisional temporary enrollments that is no earlier than March 1, 2020.

Under section 1135(b)(1)(B), CMS is also approving Delaware's request to temporarily cease revalidation of providers who are located in Delaware or are otherwise directly impacted by the emergency.

These provider enrollment emergency relief efforts also apply to the Children's Health Insurance Program (CHIP) to the extent applicable.

Duration of Approved Waivers

Unless otherwise specified above, the section 1135 waivers described herein are effective March 1, 2020 and will terminate upon termination of the public health emergency, including any extensions. In no case will any of these waivers extend past the last day of the public health emergency (or any extension thereof).