1135 Waivers

April 8, 2020

*This is informational material and does not constitute legal advice regarding any specific situation.
Purpose of 1135 Waivers

- Sufficient health care items and services are available to meet the needs of Medicare, Medicaid and CHIP beneficiaries

- Health care providers that provide such services in good faith can be reimbursed for them and not subjected to sanctions for noncompliance, absent any fraud or abuse
Objectives

Scope
Federal Requirements only, not state licensure.

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.
What Waivers Do Not Provide

1135 waivers:
- Are not a grant or financial assistance program
- Do not allow reimbursement for services otherwise not covered
- Do not allow individuals to be eligible for Medicare who otherwise would not be eligible
- Should NOT impact any response decisions, such as evacuations
- Do not last forever and appropriateness may fade as time goes
Possible 1135 Waivers or Modifications

- Conditions of Participation (CoPs) or other certification requirements
- Licensure for physicians or others to provide services in affected state
- Emergency Medical Treatment and Labor Act (EMTALA) sanctions
- Stark Self-Referral Sanctions
- Medicare Advantage out of network providers
- HIPAA
Considerations for Waiver Authority

- Scope and severity of 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?
To Issue Waivers

Presidential Declaration: National Emergencies Act or the Stafford Act

+ HHS Secretary Declaration: Public Health Emergency

= Section 1135 Waivers
1135 Waiver Request

- Provider Name/Type
- Full Address (including county/city/town/state) CCN (Medicare provider number)
- Contact person & contact information for follow-up questions should Region need additional clarification.
- Brief summary of why waiver needed
- Consideration (type of relief/regulatory requirement seeking to be waived)
# Email Addresses for CMS Regional Offices

<table>
<thead>
<tr>
<th>Regional Office</th>
<th>States</th>
<th>Email</th>
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</thead>
<tbody>
<tr>
<td>Atlanta RO</td>
<td>Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee</td>
<td><a href="mailto:ROATLHSQ@cms.hhs.gov">ROATLHSQ@cms.hhs.gov</a></td>
</tr>
<tr>
<td>Dallas RO</td>
<td>Arkansas, Louisiana, New Mexico, Oklahoma, Texas</td>
<td><a href="mailto:RODALDSC@cms.hhs.gov">RODALDSC@cms.hhs.gov</a></td>
</tr>
<tr>
<td>Northeast Consortium</td>
<td>Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia, New York, New Jersey, Puerto Rico, Virgin Islands, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont</td>
<td><a href="mailto:ROPHIDSC@cms.hhs.gov">ROPHIDSC@cms.hhs.gov</a></td>
</tr>
<tr>
<td>Midwest Consortium</td>
<td>Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin, Iowa, Kansas, Missouri, Nebraska</td>
<td><a href="mailto:ROCHISC@cms.hhs.gov">ROCHISC@cms.hhs.gov</a></td>
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1135 Waiver Review Process

- Within defined Emergency Area?
- Is there an actual need?
- What is the expected duration?
- Can this be resolved within current regulations?
- Will Regulatory relief requested actually address stated need?
- Should individual or blanket waiver be considered?
Waiver Duration

- Typically 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.
Waiver Duration

- Waivers for EMTALA (for public health emergencies that do not involve pandemic disease) & HIPAA requirements limited to 72-hour period beginning upon implementation of hospital disaster protocol.

- Waiver of EMTALA requirements for emergencies that involve pandemic disease last until termination of pandemic-related public health emergency. 1135 waiver authority applies only to Federal requirements & does not apply to State requirements for licensure or conditions of participation.
Expectations of Waived Providers

- **When Requested:** Provide sufficient information to justify actual need.

- **When Waived:** Will be required to keep careful records of patients to whom you provide services, in order to ensure that proper payment may be made.

- **When Normal Operations Resume:** Must resume compliance with normal rules and regulations as soon as you are able to do so.
Current Blanket Waivers for Hospitals, Psychiatric Hospitals, and CAHs, including Cancer Centers and Long-Term Care Hospitals (LTCHs)
Blanket Waiver Modifications

- Emergency Medical Treatment & Labor Act (EMTALA)
- Verbal Orders
- Reporting Requirements
- Patient Rights
- Sterile Compounding
- Detailed Information Sharing for Discharge Planning for Hospitals and CAHs
- Limiting Detailed Discharge Planning for Hospitals
Blanket Waiver Modifications

- Medical Staff
- Medical Records
- Flexibility in Patient Self Determination Act Requirements (Advance Directives)
- Physical Environment
- Telemedicine
- Physician Services
- Anesthesia Services
Blanket Hospital Waiver Modifications

- Utilization Review
- Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments
- Emergency Preparedness Policies and Procedures
- Quality Assessment and Performance Improvement Program
- Nursing Services
- Food and Dietetic Services
Blanket Hospital Waiver Modifications

- Respiratory Care Services
- CAH Personnel Qualifications
- CAH Staff Licensure
- CAH Status and Location
- CAH Length of Stay
- Temporary Expansion Locations
All Approved State Waivers Website

CMS Oversight

- Remains committed to ensuring continuity of oversight activities during national public health emergency
- Continue to work State Survey Agencies & accrediting organizations, charged with surveying Medicare & Medicaid providers
- Continue to monitor program operations to support proper enrollment & accurate billing practices
- Coordinate oversight activities with OIG & GAO
# Helpful Website Resources

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<th>Resource</th>
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<tr>
<td>Medicare Fee-For-Service Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With an 1135 Waiver</td>
<td><a href="https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf">https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf</a></td>
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