

1135 Waivers in Covid-19

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What is an 1135 Waiver?

- 1135 Waivers allow HHS to waive various administrative requirements to increase access to medical services during a time of national emergency

The waivers ensure that sufficient health care items and services are available to meet the needs of Medicare, Medicaid and CHIP beneficiaries, and that health care providers that provide such services in good faith can be reimbursed for them and not be subjected to sanctions for noncompliance, absent any fraud or abuse.



Result of 9/11



When can 1135 Waivers be issued?

- There are *two* requirements that must be met for 1135 Waivers to be issued:

Presidential declaration of disaster or emergency under the Stafford Act or National Emergencies Act

AND

HHS Secretary declares a public health emergency under Section 319 of the Public Health Service Act

Both of these requirements have been met as of March 13, 2020.

Scope of 1135 Waivers

Scope

- Federal requirements only; not state licensure or conditions of participation.

Purpose

- Allows reimbursement during an emergency or disaster even if providers can't comply with certain requirements that would under normal circumstances prohibit Medicare, Medicaid or CHIP payment

Duration

- Begins as of the effective date of the declared emergency. In this instance, they are retroactively effective as of March 1, 2020. Ends no later than the termination of the emergency period, or 60 days from the date the waiver or modification is published, unless the HHS Secretary extends the waiver by notice for additional periods of up to 60 days.

What don't 1135 Waivers do?

- 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 on.



Two types of 1135 Waivers

Medicare Blanket Waivers

CMS implements specific waivers or modifications on a “blanket” basis when a determination has been made that all similarly situated providers in the emergency area need such a waiver or modification.

Once approved, these waivers apply automatically to all applicable providers and suppliers. Providers and suppliers do not need to apply for an individual waiver if a blanket waiver is issued by CMS.

Provider/Supplier Individual Waivers

Individual waivers can be issued for states, providers or suppliers. These only need to be applied for if something is needed beyond what is provided under an existing blanket waiver.

Two new areas in this emergency are:

- COVID-19 facility setup, such as transfer from SNF, HH, etc. to another location (e.g. a hotel used as a temporary treatment facility)
- Medical evaluation at drive-thru testing locations



Already Issued Blanket Waivers for COVID-19

- Waivers and Flexibilities for Hospitals and other Healthcare Facilities
 - Skilled Nursing Facilities (SNFs)
 - Critical Access Hospitals
 - Acute Care Hospitals
 - Inpatient Psychiatric Services
 - Inpatient Rehabilitation Services
 - Long-Term Care Acute Hospitals
 - Home Health Agencies
 - Hospice
- Provider Licensing and Enrollment
- Suspension of Enforcement Activities
- Telehealth
- Signature Requirements
- Financial Relief for Medicare Providers
- [Link to Blanket Waiver Information](#)



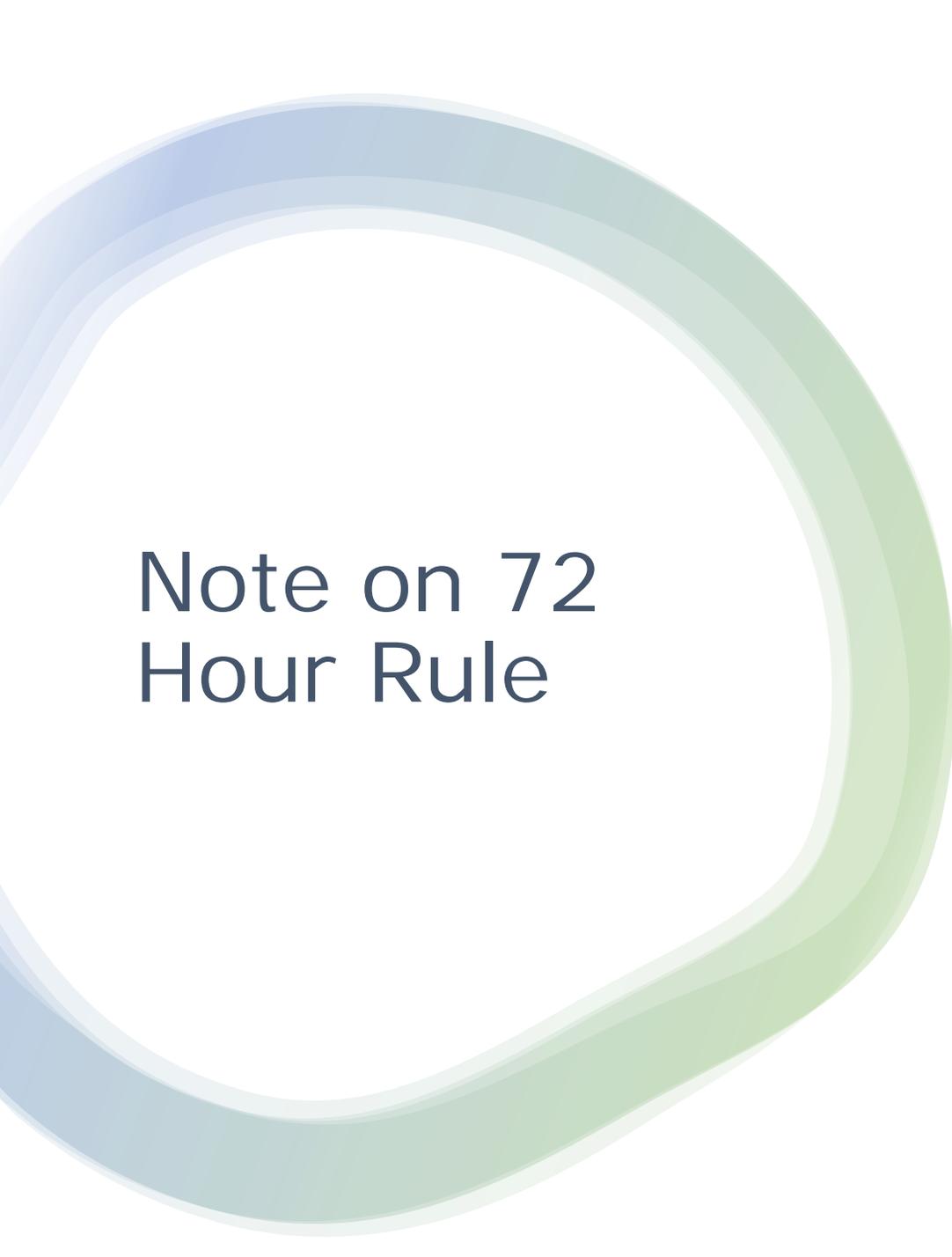
Special Waivers

Emergency Medical Treatment and Active Labor Act (EMTALA)

- Only two are available under the statute:
 - Transfer of an individual who has not been stabilized, if the transfer arises out of an emergency
 - Redirection to another location to receive a medical screening exam under a state emergency preparedness or pandemic plan.
- For the duration of the COVID-19 emergency, CMS is waiving the enforcement of section 1867(a) of the Social Security Act (or EMTALA) to allow for screening at a location offsite from the hospital's campus.

Physician Self-Referral (Stark) Law

- All requests for waiver of sanctions under the physician self-referral law related to COVID-19 should be sent to 1877CallCenter@cms.hhs.gov and include the words "Request for 1877(g) Waiver" in the subject line. All requests should include the following minimum information:
 - Name and address of requesting entity
 - Name, phone number and email address of person designated to represent the entity
 - CMS Certification Number (CCN) or Taxpayer Identification Number (TIN)
 - Nature of request



Note on 72 Hour Rule

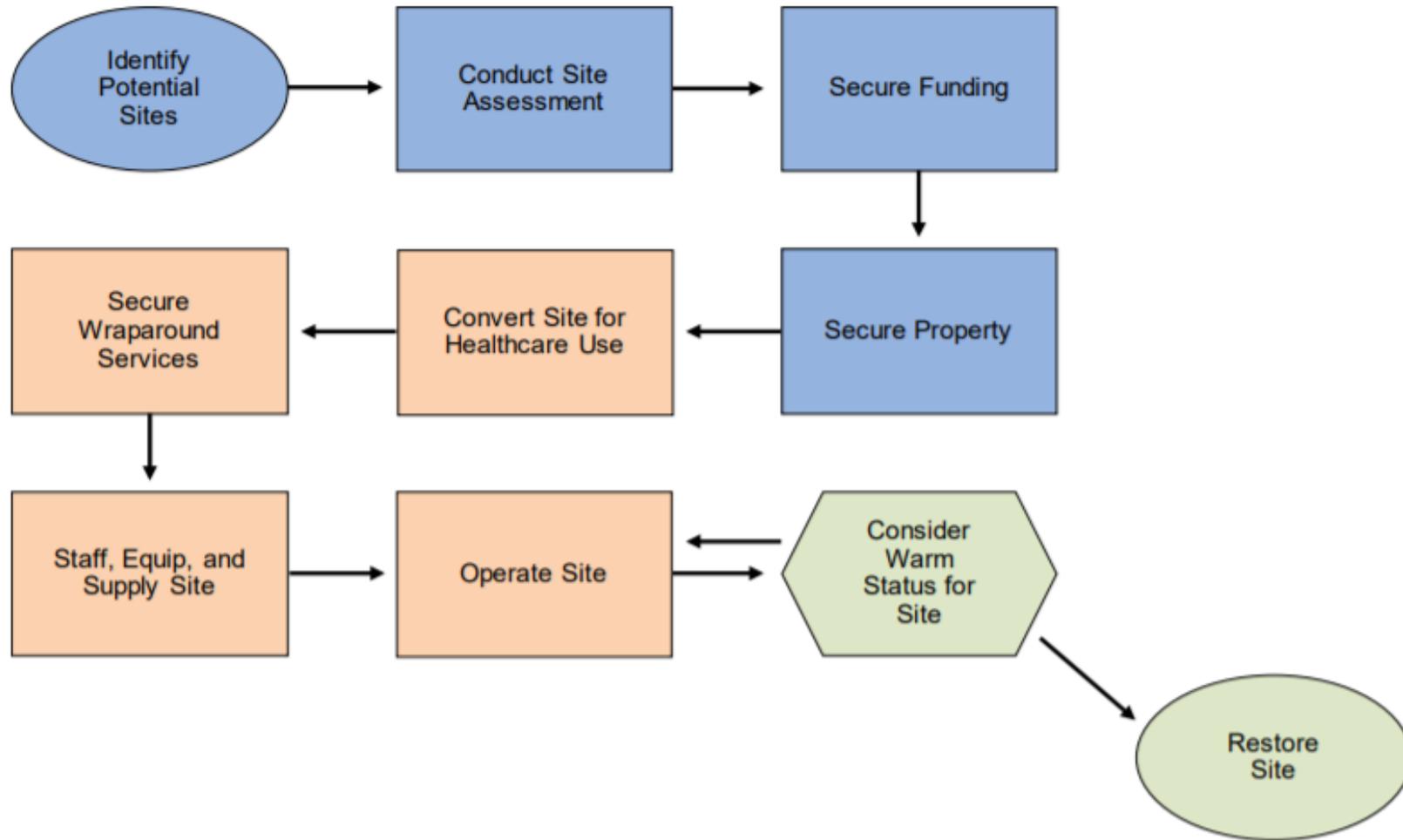
- Under other circumstances, hospitals only have 72 hours to operate under waived requirements for EMTALA and HIPAA.
- 1135 allows for extended leeway in pandemics for EMTALA, but not for HIPAA.



Emergency Preparedness Waiver

- Emergency Preparedness Policies and Procedures. CMS is waiving the requirement that the hospital develop and implement emergency preparedness policies and procedures, and the requirement that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals, and volunteers. This would not be an expectation for the surge site. This waiver applies to hospitals, and removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.

1.3 ACS Process Flowchart





Is your need covered by a Blanket Waiver?

- You DO NOT have to make a request for an accommodation covered by a blanket waiver that has already been issued.
- Additionally, you DO NOT have to notify CMS if you are taking action in accordance with a waiver during the valid waiver time period.

Waiver Authority and Review Process

Authority Considerations

- 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?

Waiver Review Process

- Is it within the defined Emergency Area?
- Is there an actual need?
- Can this be resolved within current regulations? What is the expected duration?
- Will the regulatory relief requested actually address the stated need?
- Should we consider individual or blanket waivers?



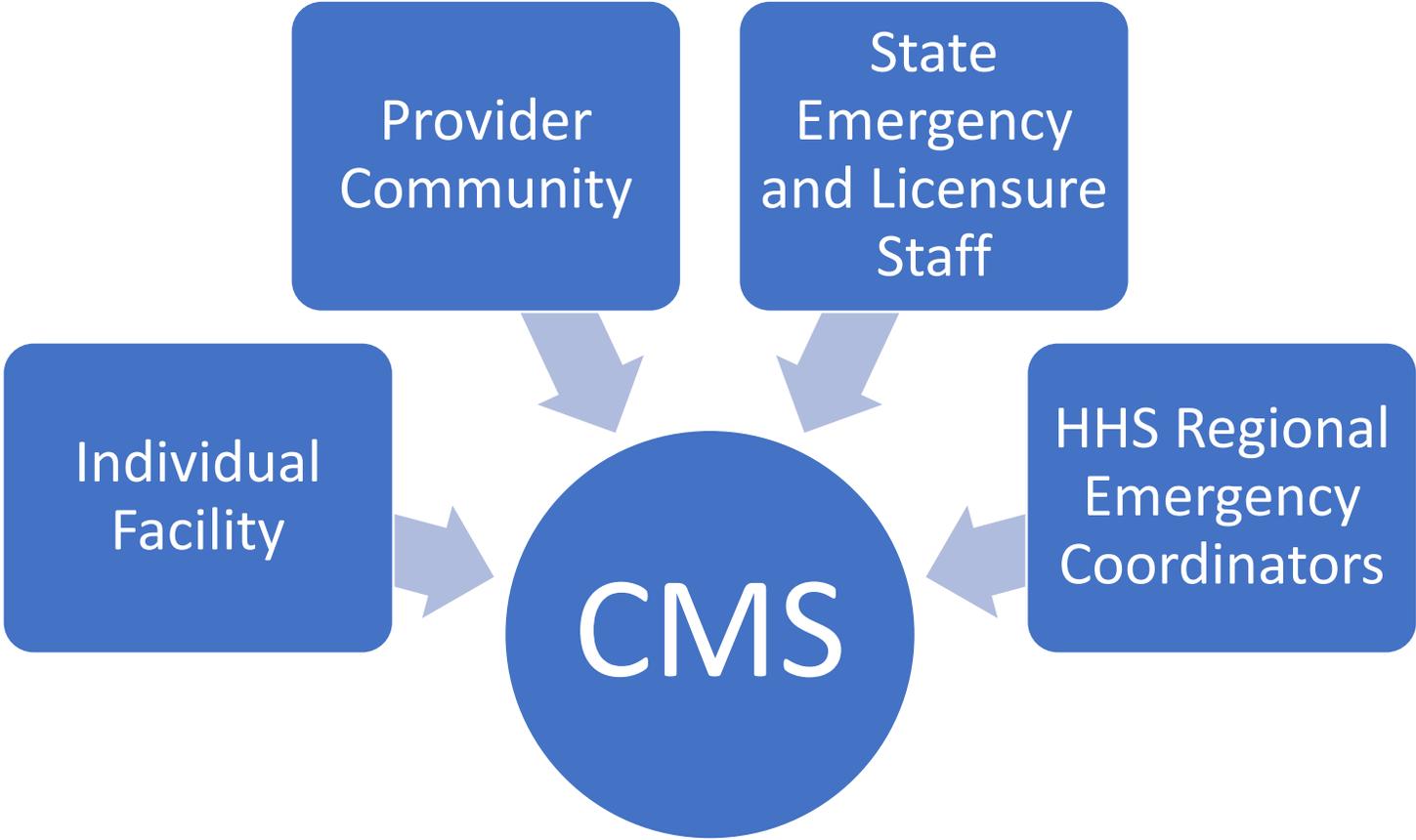
How to Request an 1135 Waiver

If you have a need for relief that is not covered under an already issued blanket waiver, you can submit a request by providing the following information:

- Full name
- Phone number
- Email address
- State/territory which is applying
- 1135 Flexibilities you are requesting

Send your requests to: 1135waiver@cms.hhs.gov

Waiver Review Inputs



Waiver Request Status

- CMS is currently reviewing the requests received from all healthcare providers. CMS will determine if frequent requests by specific providers or suppliers may be appropriate for a blanket waiver.
- CMS recommends all healthcare entities to monitor waivers approved, including blanket waivers available at:
<https://www.cms.gov/AboutCMS/Agency-Information/Emergency/EPRO/CurrentEmergencies/Current-Emergencies-page>

Expectations of Waived Providers

Request

Provide sufficient information to justify actual need.



Waived

Providers and suppliers will be required to keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made.



Normal Ops

Providers must resume compliance with normal rules and regulations as soon as they are able to do so.

Questions?

§1135 Waivers In Effect: Roadmap

- • §1135 waivers became available when the president declared an emergency on March 13, 2020
- • Waivers are for specific CMS requirements and are in these categories:
 - Facilities & Licensing
 - Workforce
 - Regulations & Conditions of Participation
 - Fiscal
 - Other Facilities
- • References to CMS waiver documents and CMS QSOG memos
- • Processes for implementing/using these waivers
- • Questions
- • Resources

§1135 Waivers In Effect: Facilities

- ❑ Physical Environment – non-hospital buildings if safety and comfort of patients and staff are sufficiently addressed
- ❑ CAH Status and Location
 - ❑ 25 beds
 - ❑ Rural location and proximity to other hospitals waived for surge sites
- ❑ Temporary Expansion of Locations
 - ❑ On-Campus, Off-Campus, including ASCs
 - ❑ Tiers 1, 2 and 3
- ❑ Housing Acute Care Patients in IPPS Units
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§1135 Waivers In Effect: Facility Licensing

- On-campus temporary or mobile structures
 - – Email mailbox.fps@state.or.us
 - – Regular Facilities Planning & Safety (FPS) regulations do not apply to temporary or mobile structures
- On- and Off-campus changes involving permanent structures use Hospital
- License Temporary Space for COVID-19 Instructions and Application
 - Increase in Bed Count
 - Changes within licensed on-campus space
 - Additions of on- or off-campus space to the hospital license
- Tiers 1, 2 or 3 including ASCs
- LSC
 - Process
- Temporary license application to mailbox.hclc@state.or.us
- 6-month license

§1135 Waivers In Effect: Workforce

- Sterile Compounding – Reusing PPE
- Medical Staff – privileging expirations and new staff
- Physician Services – Requirement that Medicare patients be under the care
 - of a physician. Use other practitioners as state EP allows
- Anesthesia Services – CRNA supervision is at discretion of hospital and state
- law
- Nursing Services
 - Nursing care plans for each patient
 - P&P for outpatient departments which may not have RNs
 - Inpatients over outpatients

§1135 Waivers In Effect: Workforce

- Respiratory Care Services – Designate in writing personnel qualified to perform specific services and supervision required
- CAH Personnel Qualifications – Minimum personnel requirements for Clinical
- Nurse Specialists, NPs & PAs
- CAH Staff Licensure – Defer to state
- Practitioner Location – Licensed in one state and providing services in another with 4 conditions
 - Enrolled in Medicare
 - Possess a valid license in the state which relates to Medicare enrollment
 - Furnishing services in a state in which emergency is occurring to contribute to
- relief effort in professional capacity
 - Not excluded from practice and that or any other state covered by 1135

§1135 Waivers In Effect: Regulations & CoPs

- EMTALA – see Emergency Medical Treatment and Labor Act (EMTALA)
- Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19)
 - On-campus – EMTALA Applies
 - Patients arriving at ED must receive MSE for EMC
- MSE can include telehealth
- Patients can wait in the car
- Can't skip MSE due to lack of PPE
 - Signage can direct patients to testing but cannot be a barrier to MSE
 - Off-campus
- ED locations – EMTALA applies
- Screening only– No EMTALA
- Drive-Through Testing – No EMTALA
 - Transfers without stabilization

§1135 Waivers In Effect: Regulations & CoPs

- Verbal Orders
 - Read-back verification
 - Delayed authentication
 - Preprinted/electronic
- Reporting Requirements – ICU deaths involving restraints
- Patient Rights
 - Timeframe for providing copies of medical records
 - Visitation
 - Seclusion in psych
- Detailed info for discharge planning
 - Waives requirement for detailed info to patients/families to use in selecting postacute care provider, but still have quality measures and consider patients goals and preferences
 - Ensure discharge to an appropriate setting with necessary medical info and goals of care

§1135 Waivers In Effect: Regulations & CoPs

- Medical Records
 - – Form and content flexibility
 - – Follow state EP
 - – Complete within 30 days
 - – Patients over paperwork
- • Telemedicine (more about this in Fiscal) – using agreements with an off-site hospital, increases access to care
 - – CMS <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-healthcare-provider-fact-sheet>
 - – OHP <https://www.oregon.gov/oha/HSD/OHP/Announcements/Oregon%20Health%20Plan%20coverage%20of%20telemedicine%20services.pdf>
- – Private Insurance
 - <https://dfr.oregon.gov/insure/health/understand/Documents/DFROHA%20Telehealth%20Guidance.pdf>

§1135 Waivers In Effect: Regulations & CoPs

- Advance Directives – do not need to provide info about AD P&P
- • P&Ps for Appraisal of Emergencies at Off-Campus Departments – P&P for evaluating emergencies not required at surge facilities
- • EP P&P – P&P not required for surge facilities
- • QAPI – focus on improvements to address the Public Health Emergency
- • Food and Dietetic Services
 - – Therapeutic diet manual not required at surge sites
- • CAH Length of Stay – 96 hours or longer
- • LTACH Length of Stay
- • Discharge to SNF Length of Stay

§1135 Waivers In Effect: Fiscal

- Utilization Review
- Extension for IPPS Wage Index Occupations Mix Survey Submission
- DMEPOS
- Provider Enrollment
- Medicare Appeals in FFS, MA and Part D
- Medicaid and CHIP
- Individual Physician Self-Referral Law

COVID-19 Response

- CMS is empowered to take proactive steps through 1135 waivers
- In constant contact with state health officials and health care providers and partners to understand new needs
- Working to make sure every stakeholder in the system is fully informed