

Non-Substantive Change Request to 0938-1384: Submissions of 1135 Waiver Request Automated Process

August 31, 2021

This is a non-substantive change request to the CMS 1135 Waiver/Flexibility Request from the ‘Submission of 1135 Waiver Request Automated Process’ that was approved as OMB number 0938-1384. In a disaster or emergency, CMS must be able to apply waivers and flexibilities to assist health care providers/suppliers in providing timely healthcare and services as well as ensure beneficiaries have continued access to care. As a result, CMS developed a publically-accessible web based form to create a standardized, user-friendly submission that’s a more efficient processing of 1135 waiver requests.

As emergencies quickly occur (e.g., Hurricane Ida), CMS would like to have flexibilities to update the values of the “Public Health Emergency” (PHE) and “Waiver Types” fields for each specific emergent event (e.g., hurricanes, wildfires, COVID-19, etc.). Allowing these flexibilities will expedite the process and prevent gaps in care for beneficiaries/healthcare providers. As a result of the million lives currently impacted by Hurricane Ida, CMS is making this urgent request. CMS is requesting approval of the following updates effective August 31, 2021 to allow the agency to quickly provide necessary assistance to those impacted by Hurricane Ida:

CMS 1135 Waiver/Flexibility Request web page

- Add a Public Health Emergency (PHE) on page 2, such that “2021 Hurricane Ida (LA and MS)” is added in the drop-down values for the “Select a Public Health Emergency” section of the web form
- Add waiver types on page 2 (new drop-down values reflected on page 3), such that the following waiver request types are added in the drop-down values for the “Waiver Request Type” portion in the “Describe Your 1135 Waiver/Flexibility Request” section of the web form:

Waiver Request Type
Flexibility for Medicare Telehealth Services - Eligible Practitioners
Flexibility for Medicare Telehealth Services - Audio-Only Telehealth for Certain Services
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - EMTALA
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Verbal Orders
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Reporting Requirements
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Patient Rights [Only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19]
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Sterile Compounding
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Detailed Information Sharing for Discharge Planning for Hospitals and CAHs
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Limiting Detailed Discharge Planning for Hospitals
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Medical Staff
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Medical Records
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Flexibility in Patient Self-Determination Act Requirements (Advance Directives)

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Waiver Request Type
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Physical Environment
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Telemedicine
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Physician Services
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Anesthesia Services
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Utilization Review
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments [With respect to surge facilities only]
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Emergency Preparedness Policies and Procedures
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Quality Assessment and Performance Improvement Program
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Nursing Services
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Food and Dietetic Services
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Respiratory Care Services
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Expanded Ability for Hospitals to Offer Long-term Care Services (“Swing-Beds”) for Patients Who do not Require Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Medicare Graduate Medical Education (GME) Affiliation Agreement
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - CAH Personnel Qualifications
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - CAH Staff Licensure
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - CAH Status and Location
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Temporary Expansion Locations
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Responsibilities of Physicians in CAHs
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - Long Term Care Hospitals - Site Neutral Payment Rate Provisions
Hospitals, Psych. Hospitals, and CAHs, including Cancer Ctrs and LTCHs - CoP for COVID-19 Vaccinations
Hospitals Classified as Sole Community Hospitals (SCHs)
Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDHs)
RHCs and FQHCs - Certain Staffing Requirements
RHCs and FQHCs - Physician Supervision of NPs in RHCs and FQHCs
RHCs and FQHCs - Temporary Expansion Locations
Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule”
Inpatient Rehabilitation Facility – Intensity of Therapy Requirement (“3-Hour Rule”)
Supporting Care for Patients in LTCHs
Care for Patients in Extended Neoplastic Disease Care Hospitals
Care for Patients in Extended Neoplastic Disease Care Hospitals - Comprehensive Care for Joint Replacement (CJR) Model
LTC Facilities and SNFs and/or NFs - PASARR
LTC Facilities and SNFs and/or NFs - Physical Environment
LTC Facilities and SNFs and/or NFs - Resident Groups
LTC Facilities and SNFs and/or NFs - Training and Certification of Nurse Aides

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Waiver Request Type
LTC Facilities and SNFs and/or NFs - Physician Visits in Skilled Nursing Facilities/Nursing Facilities
LTC Facilities and SNFs and/or NFs - Resident Roommates and Grouping
LTC Facilities and SNFs and/or NFs - Resident Transfer and Discharge
LTC Facilities and SNFs and/or NFs - Physician Services - Physician Delegation of Tasks in SNFs
LTC Facilities and SNFs and/or NFs - Physician Services - Physician Visits
LTC Facilities and SNFs and/or NFs - Physician Services - Note to Facilities
LTC Facilities and SNFs and/or NFs - Quality Assurance and Performance Improvement (QAPI).
LTC Facilities and SNFs and/or NFs - In-Service Training
LTC Facilities and SNFs and/or NFs - Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities
LTC Facilities and SNFs and/or NFs - Clinical Records
LTC Facilities and SNFs and/or NFs - Paid Feeding Assistants
HHAs - Initial Assessments
HHAs - Waive Onsite Visits for HHA Aide Supervision
HHAs - Allow OTs, PTs, and SLPs to Perform Initial and Comprehensive Assessment for all Patients.
HHAs - 12-hour Annual In-service Training Requirement for Home Health Aides
HHAs - Detailed Information Sharing for Discharge Planning for Home Health Agencies
HHAs - Clinical Records
HHAs - Training and Assessment of Aides
HHAs - Quality Assurance and Performance Improvement (QAPI)
Hospice - Waive Requirement for Hospices to Use Volunteers
Hospice - Comprehensive Assessments
Hospice - Waive Non-Core Services
Hospice - Waived Onsite Visits for Hospice Aide Supervision
Hospice - Hospice Aide Competency Testing Allow Use of Pseudo Patients
Hospice - 12 hour Annual In-service Training Requirement for Hospice Aides
Hospice - Annual Training
ESRD Facilities - Training Program and Periodic Audits
ESRD Facilities - Defer Equipment Maintenance & Fire Safety Inspections
ESRD Facilities - Emergency Preparedness
ESRD Facilities - Ability to Delay Some Patient Assessments
ESRD Facilities - Time Period for Initiation of Care Planning and Monthly Physician Visits
ESRD Facilities - Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation
ESRD Facilities - Home Dialysis Machine Designation – Clarification
ESRD Facilities - Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded
ESRD Facilities - Dialysis Patient Care Technician (PCT) Certification
ESRD Facilities - Transferability of Physician Credentialing
ESRD Facilities - Expanding Availability of Renal Dialysis Services to ESRD Patients - Furnishing Dialysis Services on the Main Premises

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Waiver Request Type
ESRD Facilities - Clarification for Billing Procedures
Physical Environment for Multiple Providers/Suppliers - Inspection, Testing & Maintenance (ITM) under the Physical Environment Conditions of Participation - Specific Physical Environment Waiver Information
Specific LSC for Multiple Providers - Waiver Information - Alcohol-based Hand-Rub (ABHR) Dispensers
Specific LSC for Multiple Providers - Waiver Information - Fire Drills
Specific LSC for Multiple Providers - Waiver Information - Temporary Construction
ICF/IID - Staffing Flexibilities
ICF/IID - Suspension of Community Outings
ICF/IID - Suspend Mandatory Training Requirements
ICF/IID - Modification of Adult Training Programs and Active Treatment
ASCs - Medical Staff
ASCs - Nursing Services
CMHCs - Quality assessment and performance improvement (QAPI)
CMHCs - Provision of Services
CMHCs- 40 Percent Rule
Ambulance Services - Medicare Ground Ambulance Data Collection System
Ambulance Services - Ambulance Treat in Place
Practitioner Locations
Modification of 60-Day Limit for Substitute Billing Arrangements (Locum Tenens)
Medicare Appeals in Fee for Service (FFS), Medicare Advantage (MA) and Part D
Medicaid and CHIP (as of 3/13/2020)

CMS 1135 Inquiry web page

- Add a Public Health Emergency (PHE) on page 5, such that “2021 Hurricane Ida (LA and MS)” is added in the drop-down values for the “Select a Public Health Emergency” section of the web form ORGANIZATION WORKFLOW: Correct an error on page 4, such that an

These changes have no impact on the previously stated burden associated with this collection.