

COVID-19 1135 Waivers

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Background



Federal law, 42 USC 1135, provides authority for the Secretary of HHS, to ensure to the maximum extent feasible, in any emergency area and during an emergency period (1) that sufficient health care items and services are available to meet the needs of individuals; and (2) that health care providers that furnish such items and services in good faith, but that are unable to comply with one or more requirements of certain identified federal laws may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

Requires:

- that the President has declared a national emergency, which occurred on March 13, 2020, regarding COVID-19.
- that the Secretary of HHS has declared a public health emergency, which Secretary Azar did on January 31, 2020, regarding COVID-19.

Declaration of Waiver



On March 13, 2020, Secretary Azar issued a declaration of waiver under 1135 authority with three sections:

1. Waiver of various federal regulations “but in each case, only to the extent necessary, as determined by [CMS] to ensure that sufficient health care items and services are available to meet the needs of individuals...”
2. Waiver of sanctions and penalties arising from noncompliance with various HIPAA privacy regulations “but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.”
3. Modification of deadlines and timetables and for the performance of required activities “but only to the extent necessary, as determined by [CMS] to ensure that sufficient health care items and services are available to meet the needs of individuals...” so that providers may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

CMS Blanket Waivers



On March 13, 2020, CMS issued a list of “blanket” waivers.

<https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf>

Hospitals

- Waiver of requirements to allow acute care hospitals to house inpatients in excluded distinct part units where the bed is appropriate for inpatient care and needed due to capacity issues related to the emergency.
- Waiver to allow acute care hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients from the psychiatric unit to an acute care bed/unit, if appropriate for psychiatric care, as needed as a result of the emergency.
- Waiver to allow acute care hospitals with excluded distinct part rehabilitation units to relocate inpatients from the rehabilitation unit to an acute care bed/unit, if appropriate for rehabilitation care, as needed, as a result of the emergency.

Critical Access Hospitals

- Waiver of the 25 bed limit.
- Waiver of the 96 hour length-of-stay limit.

EMTALA Waiver



- No blanket waivers have been issued by CMS for EMTALA. 1135 authority requires additional CMS action.
- Region V has confirmed that the March 13, 2020, declaration by Secretary Azar is not a blanket waiver.
- Remember even without a waiver, EMTALA permits:
 - Use of alternative on-campus screening sites.
 - Use of alternative off-campus screening sites. May be publicized and request individuals to go there. However, if individual comes to the hospital, must still provide MSE and appropriate treatment/transfer.
- Individual hospitals may seek specific 1135 EMTALA waiver from Region V.

HIPAA Waiver



The waiver by Secretary Azar on March 13, 2020, regarding HIPAA provisions, needed no additional CMS/HHS action, waives sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations:

- the requirement to obtain a patient’s agreement to speak with family members or friends (as set forth in 45 C.F.R. § 164.510(b));
- the requirement to honor a request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510(a));
- the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and
- the patient’s right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522).

This is a *limited* waiver and that it applies to hospitals *only* when the hospital has instituted disaster protocols and *only* for a period of time not to exceed 72 hours from implementation of the hospital disaster protocols.

Other HIPAA Relief



Additionally, OCR issued in a “Notice of Enforcement Discretion” (not a 1135 waiver) announced it would not enforce penalties for HIPAA violations against health care providers that serve patients through everyday communications technologies during the public health emergency:

- Allows use of any non-public facing remote communication product that is available to communicate with patients for any telehealth treatment or diagnostic purpose. Services do *not* have to be directly related to COVID-19.
- Technology includes: Apple FaceTime, Facebook Messenger video chat, Google Hangouts video or Skype. Use of public facing applications, such as Facebook Live, are *not* permitted.
- Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications.

This is not a *limited* waiver. Applies immediately and is currently effective.

Telehealth Waiver



CMS issued additional reimbursement related waiver regarding expanded telehealth services on March 17, 2020.

<https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>

- Covered telehealth services may be provided regardless of patient location (e.g., their homes); there are no setting limitations.
- Professionals may bill for these services, and Medicare will pay the same amount as if the service was furnished in person.
- Health care providers may use additional forms of everyday communications technologies to provide these services (see HIPAA guidance).
- An established patient relationship requirement is *not* required.
- Services may be provided to *any* patient. It is not required that these be services for patients being treated for COVID-19.

Resources



<https://www.bricker.com/resource-center/COVID19/key-resources/resource/hospitals-and-health-systems-covid-19-implications-and-resources-1112>

<https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>

Resources



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