

Medicare 1135 Waivers & Two Interim Final Rules Enabling Health System Expansion

Medicare 1135 Waivers & Two Interim Final Rules

- CMS has two critical roles:
 - Ensure Medicare beneficiaries receive safe and effective care during the COVID-19 Public Health Emergency (PHE).
 - Ensure Medicare payment/coverage policies during the COVID-19 PHE do not impede providers working to expand capacity to treat patients.
- In light of the PHE, CMS can waive certain pre-approval requirements, federal licensing requirements, EMTALA, Stark Law, and “certain deadlines and timetables for performance of required activities.”
- CMS is enabling significant health system flexibility during the PHE through waivers and regulatory flexibility.

Medicare 1135 Waivers & Interim Final Rules

Enabling Health System Expansion

- **Waivers** – CMS issued national (“blanket”) §1135 waivers for certain hospital CoPs, provider-based rules, and the physician self-referral law (“Stark law”)
 - Enables rapid expansion of hospital services in on-/off-campus clinical/non-clinical space, including in partnership with other entities
 - Allows other facility types (e.g., ASCs) to become hospitals, subject to meeting more flexible CoPs in place during the PHE as well as streamlined enrollment and cost-reporting requirements
 - Allows hospitals and other providers to offer things like free meals, childcare or laundry to healthcare workers by waiving sanctions under the Stark law
- **Regulatory Flexibility** – CMS published two interim final rules, with comment periods
 - Clarifies rules for hospitals to furnish inpatient services under-arrangement with other providers
 - Clarifies when hospitals can furnish outpatient services in the patient’s home or other expansion site
 - Establishes process for hospital outpatient departments to seek exception from lower payments when temporarily relocating due to the PHE
 - Expands physician supervision flexibilities for inpatient/outpatient hospitals services
 - Expands services that can be furnished through telehealth
 - Expands types of practitioners that can furnish telehealth
 - Expands coverage of ambulance transport to additional sites

Other Support – CARES Act Provisions for Acute Care Hospitals

- New \$100b fund for providers responding to the COVID-19 PHE (grants – HHS is administering)
 - Initial \$30b allocated in early April, as of 4/28/20 HHS had begun distribution of an additional \$20b¹
- Eliminates sequestration (2% reduction) to Medicare payments 5/1/20-12/31/20
 - CMS took action to ensure provision is effective for claims starting 5/1/20²
- 20% increase to IPPS DRG weight for patients diagnosed with COVID-19 during the PHE
 - CMS took action to implement this provision for discharges on or after 1/27/20³
- Expands CMS accelerated payment program
 - CMS successfully allocated over \$100b under this program and as of 4/26/20, CMS was reevaluating the amounts that would be paid⁴
- Legislation includes other non-hospital related health provisions

¹: <https://www.hhs.gov/about/news/2020/04/28/eligible-providers-can-submit-information-to-receive-additional-provider-relief-fund-payments.html>

² https://www.cms.gov/outreach-and-education/outreachffsprovpartprogprovider-partnership-email-archive/2020-04-10-mlnc-se#_Toc37418832

³ <https://www.cms.gov/files/document/se20015.pdf>

⁴ <https://www.cms.gov/newsroom/press-releases/cms-reevaluates-accelerated-payment-program-and-suspends-advance-payment-program>

Expanding Capacity: Local Private vs. Public (Federal Emergency Management Agency, Department of Defense, State and Local Gov.) Approaches



Local Private Hospital

- Hospital expands by repurposing clinical or non-clinical spaces
- Has existing CCN and uses their resources for operations (e.g., capital, equipment, labor)
- Hospital obtains appropriate licensing and other state approvals as needed
- Medicare pays hospital for care furnished in new sites under applicable payment system
- Professionals bill under MPFS

Military hospital ships docked in a United States port and temporary military field hospitals erected in the United States in response to a mission assignment from the Federal Emergency Management Agency (FEMA) do not bill civilians or the Medicare program for any services rendered.



Federally-Developed, Locally-Staffed

- FEMA/DOD/State establishes new hospital-level care site, such as convention center, hotel, tent, etc.
- Facility operations and staffing handed off to existing Medicare-enrolled hospital(s)
- Hospital (in partnership with state or local gov) obtains appropriate licensing, other approvals
- Medicare largely pays hospital for care furnished in new sites under applicable payment system
- Professionals bill under MPFS

CMS Example Scenarios: Provider Flexibilities



Ambulatory Surgical Center (ASC)

ASCs can become hospitals under new streamlined process. They can also work under arrangement with existing hospital to create a temporary expansion site.



FEMA/DOD/State Facility

Newly established care locations run by the state or federal government will furnish care to patients during the PHE.



Skilled Nursing and/or Nursing Facility (SNF/NF)

SNF/NFs can work with hospitals under arrangements to be able to provide inpatient acute care to Medicare beneficiaries.



Hospitals & Practitioners

- Hospitals can treat patients in existing clinical space, new temporary expansion sites, or triage patients to other care sites based on resources and COVID-19 status.
- Medicare-enrolled physicians and practitioners can furnish covered services in all of these care settings and bill for those services under the Medicare physician fee schedule



Long-Term Care Hospital (LTCH)

LTCHs meet Medicare hospital requirements and can provide inpatient acute care to Medicare beneficiaries. Medicare's 50% rule will be dropped during the PHE (CARES Act).



Inpatient Rehab Facility (IRF)

IRFs meet Medicare hospital requirements and can provide inpatient acute care to Medicare beneficiaries. Medicare's 3-hour rule will be dropped during the PHE (CARES Act).

CMS Example Scenarios: Hospital Expansion of Inpatient Beds



Medicare-enrolled Hospital

- Has existing CCN
- IPPS (~3,300), LTCH PPS (~380), Critical Access Hospital (~1300)
- Wants to expand inpatient capacity during PHE



Policies Applying to All Scenarios

- CMS will not require submission of amended 855A enrollment form during PHE.
- CMS, states and accreditors have stopped compliance survey activities.
- State licensure of new spaces/bed may be required depending on state rules.
- Payments to professionals would also need to be considered – below is specific to facility payments



Example: Parking Lot Hospital Tent

- Hospital erects a tent in their parking lot to provide covered services
- Care provided in tent must meet refined CoPs.
- Hospital can bill under existing CCN following standard billing practices for inpatient and outpatient services.
- Hospital should add “DR” condition code for patients in all new locations, including tents.



Example: Repurposes Distinct Part Unit Beds

- Hospital repurposes distinct part unit beds for use as short stay acute inpatient beds.
- Care furnished in new inpatient beds must meet refined CoPs; noting new flexibilities and waivers
- Hospital can bill under existing CCN following standard billing practices for inpatient services.
- Hospital should add “DR” condition code for patients in all new locations, including repurposed beds.



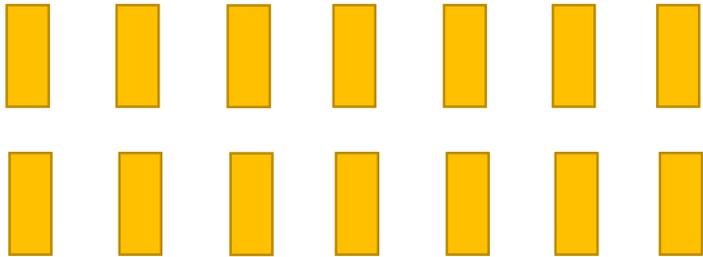
Example: Rents Available Space (closed hospitals, empty building)

- Hospital transforms a new empty building to inpatient space
- Care furnished in new inpatient space must meet refined CoPs.
- Hospital can bill under existing CCN following standard billing practices for inpatient services.
- Hospitals should add “DR” condition code for patients in all new locations, including the convention center.

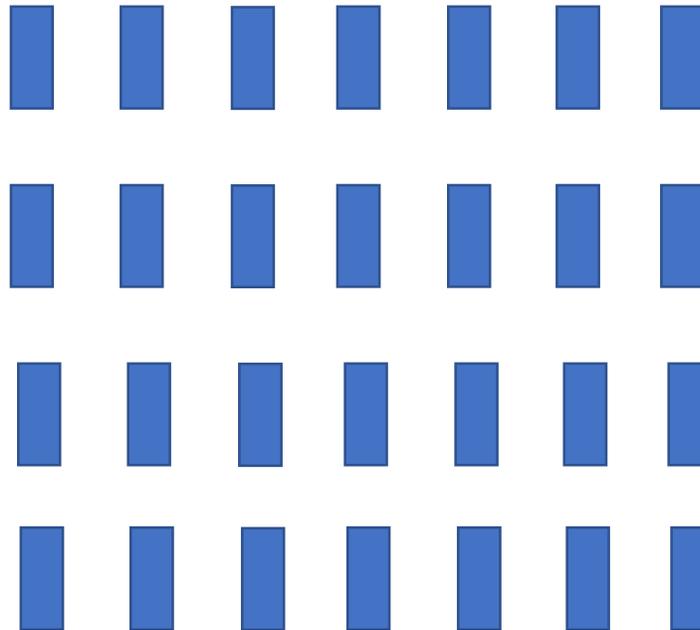
CMS Example Scenarios: Shared Operations in Temporary Expansion Site

Convention Center

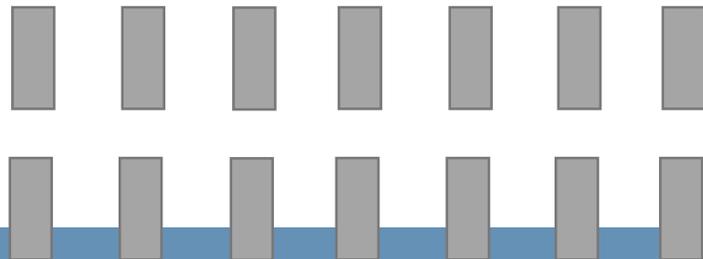
Hospital A (Capacity = 14 Beds)



Hospital C (Capacity = 28 Beds)



Hospital B (Capacity = 14 Beds)



Key Attributes

- This example temporary expansion site is jointly managed by 3 different hospitals.
- Each hospital manages its own “section” like a separate hospital – they provide the staff and resources necessary for site operations, including the clinical staff and other necessary services (pharmacy, lab, radiologic, dining) required to furnish inpatient/outpatient care.
- Certain resources are jointly purchased where it makes sense for economies of scale and operations (e.g., building power, oxygen and other DME)
- Each hospital bills separately for care furnished to their patients. Patients moving from one hospital’s section to another hospital’s section are considered inpatient transfers and billed as such.

CMS Example Scenarios: ASC to Hospital Conversion



Ambulatory Surgical Center

Example: Ambulatory Surgical Center Enrolls as a Hospital

- Medicare-certified ASC enrolls as a “temporary expansion site” hospital using new streamlined attestation process
- Newly-enrolled hospital must meet refined hospital Conditions of Participation in effect during PHE
- Medicare would provide a CCN for the newly-enrolled hospital
- Newly-enrolled hospital can bill using new CCN following standard billing practices for inpatient and outpatient services.
- The newly-enrolled hospital should add “DR” condition code for patients in all new locations



Medicare-enrolled Hospital

CMS Example Scenarios: Care Furnished in Patients' Homes



Hospital Inpatient

Under 1135 waivers and new under arrangements policy hospitals can consider the patient's home a temporary expansion site during the PHE. Hospitals would need ensure that the applicable expansion site meets all of the remaining conditions of participation, including the ability to provide laboratory and pharmacy services, 24-hour nursing care, and food services, among others. Any arrangement to furnish inpatient care in the beneficiary's home must be consistent with any state licensing or other regulatory requirements active under the state's emergency preparedness or pandemic plan.



Hospital Outpatient Department

Under 1135 waivers hospitals can treat patients homes as provider-based departments (PBDs) during the PHE while the patient is enrolled as an outpatient. The PBDs can bill for medically necessary outpatient therapeutic services furnished in the home, assuming all other applicable requirements are met (including, to the extent not waived, the hospital conditions of participation). Hospital must be aware if patient is under a home health plan and not furnish services that are being furnished by home health agency.



Patients Home



Practitioners

Practitioners can care for patients in their homes with face-to-face visits by performing house calls or via telehealth



Physician Practices Auxiliary Personnel

Physician practices can work with auxiliary personnel to furnish care incident to the physician's service in the patient's home. This could include, for example, infusions, wound care and other services. Under these approaches, the physician practice would bill for these services under the Physician Fee Schedule and pay the auxiliary personnel (e.g., home health agency or home infusion provider) directly.



HHAs

HHAs can furnish care in the beneficiaries home during the PHE. In-person care can be supplemented by virtual care.

CMS Example Scenarios: Practitioners



Patient's Home

Practitioners can care for patients in their homes with face-to-face visits by performing house calls or via telehealth



Skilled Nursing Facility and/or Nursing Facility (SNF/NF), Inpatient Rehab Facility (IRF), Long-Term Care Hospital (LTCH), Ambulatory Surgical Center (ASC)

Practitioners care for patients with face-to-face visits or via telehealth in these settings that provide inpatient acute care beds and meet Medicare hospital requirements.



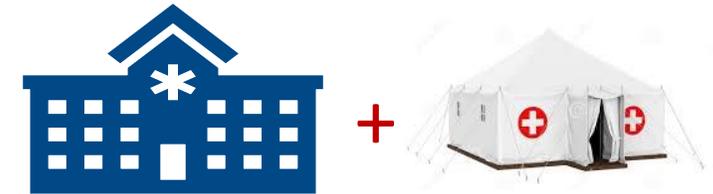
Practitioners

Practitioners can treat patients with or without COVID in a variety of settings, including temporary expansion sites, and bill for services under the Medicare Physician Fee Schedule.



Ambulatory Practices

Practitioners can care for patients via telehealth or with face-to-face visits using measures to avoid potential COVID transmission between patients (space scheduling and rooms, patients avoid waiting rooms, etc.).



Hospital Inpatient/Outpatient

Practitioners can care for hospital inpatients and outpatients with face-to-face visits or via telehealth as part of a medical practice or as an independent practice. Hospitals include the temporary expansion sites where inpatient and outpatient care is being furnished.

Key Links

CMS Waiver and Flexibilities Website: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>

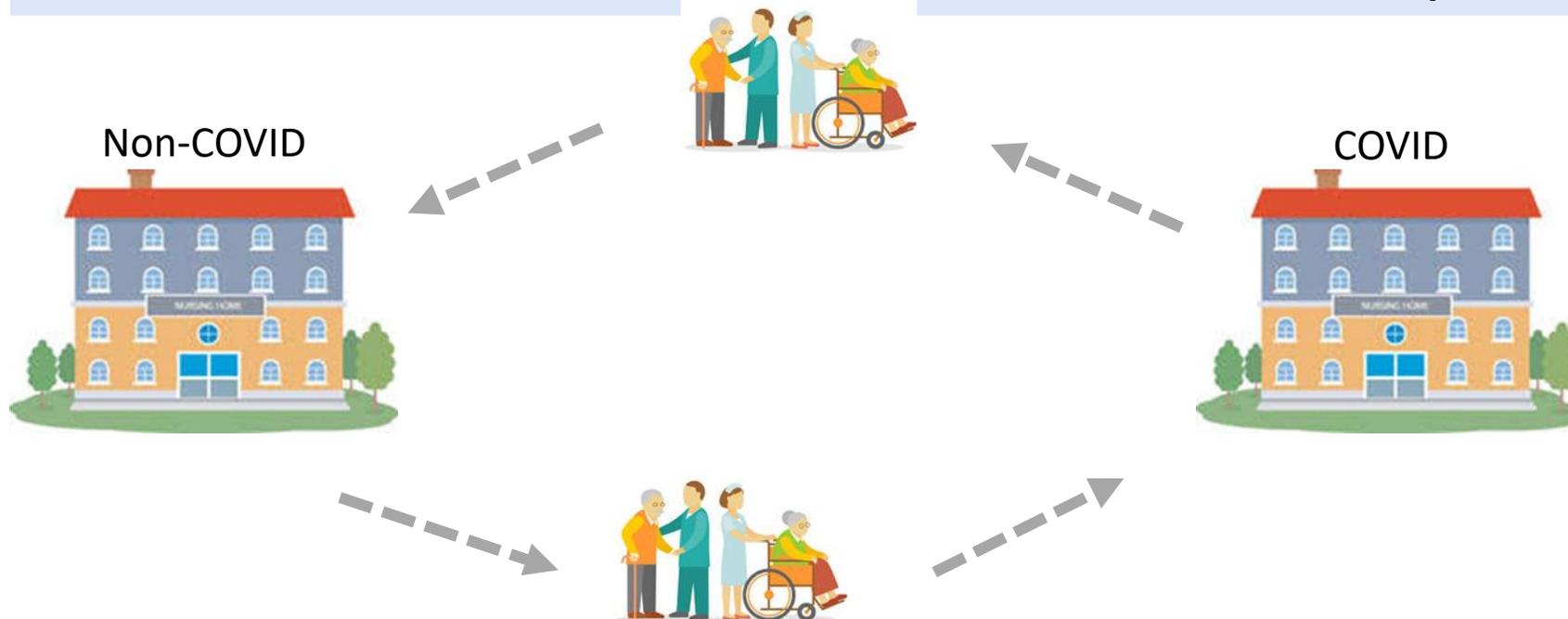
Regulatory Flexibilities Press Release: <https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19>

Regulatory Flexibilities Fact Sheet: <https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient>

Appendix A: Additional PHE Flexibilities for Post-Acute Providers

CMS Example Scenarios: SNFs

Two or more Certified SNF/NFs transfer patients between facilities to create a COVID and Non-COVID Facility. Allowed under Blanket Transfer Waiver without additional approval. Each certified SNF bills Medicare for the residents in their facility.



- CMS is waiving requirements in 42 CFR 483.10(c)(5); 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), (c)(9), and (d); and § 483.21(a)(1)(i), (a)(2)(i), and (b) (2)(i) (with some exceptions) to allow a long term care (LTC) facility to transfer or discharge residents to another LTC facility solely for the following cohorting purposes: Transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents;
- Transferring residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents to prevent them from acquiring COVID-19; or
- Transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days.

Transfer residents from one or more Certified SNFs to a Non-Certified Location that is state approved and where residents must be cared for by SNF staff: Medicare reimbursement remains with the SNF caring for patients in the new location. This location could be utilized by multiple SNFs, providing care with their own staff.



- CMS is waiving requirements related at 42 CFR 483.90, specifically the following: Provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under § 483.90 to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there are needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 are available while protecting other vulnerable adults.
- These requirements are also waived when transferring residents to another facility, such as a COVID-19 isolation and treatment location, with the provision of services “under arrangements,” as long as it is not inconsistent with a state’s emergency preparedness or pandemic plan, or as directed by the local or state health department. In these cases, the transferring LTC facility need not issue a formal discharge, as it is still considered the provider and should bill Medicare normally for each day of care. The transferring LTC facility is then responsible for reimbursing the other provider that accepted its resident(s) during the emergency period.

Transfer of COVID residents to Federal/State Run Facility staffed with Federal or State Personnel: Transfers by Order of Governmental Authority (e.g., FEMA) and no reimbursement to SNF.



No waiver necessary as long as transfer is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department

Flexibility for Inpatient Rehabilitation Facilities (IRFs) & Long-Term Care Hospitals (LTCHs)

Freestanding IRFs and “distinct part unit” (rehab units part of an acute care facility) IRFs, and LTCHs are considered hospitals for Medicare enrollment and oversight purposes. They can furnish and bill Medicare for covered inpatient services, and, similar to other hospitals, they can take use waivers of CoP waivers and other flexibilities to expand capacity during the PHE. Below are additional flexibilities specific to IRFs and LTCHs that enable them to treat more acute beneficiaries during the PHE.

IRFs

- Rehabilitation physicians can conduct the required 3 face-to-face visits per week by telehealth during the PHE. [IFC 1]
- During the PHE, rehabilitation physicians do not need to conduct the post-admission evaluation. [IFC 1]
- IRFs admitting patients in response to the PHE can exclude those patients for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the “60 percent rule”). [Waiver]
- Acute care hospitals with inpatient rehabilitation units can relocate inpatients from rehabilitation unit to an acute care unit as a result of this PHE. [Waiver]
- Acute care hospitals can house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit’s beds are appropriate for acute care inpatients. [Waiver]
- CMS is implementing Section 3711(a) of the Cares Act (PL 116-136), which requires CMS to waive the requirement that IRF patients generally receive at least 15 hours of therapy per week.

LTCHs

- LTCHs can exclude patients admitted or discharged in order to meet the demands of the emergency from the 25-day average length of stay requirement, which allows these facilities to be paid as LTCHs. [WAIVER]
- CMS is implementing Section 3711(b) of the Cares Act, which requires CMS to waive the LTCH 50% rule (at least 50% of patients meet LTCH criteria), as well as the site-neutral payment rate (lower rate applied when LTCH criteria not met).

Flexibility for Home Health Agencies (HHAs)

Home health is critical to helping Medicare beneficiaries stay at home and stopping community spread of COVID-19. In addition to the below, home health agencies can partner with physician practices (under “auxiliary personnel” arrangements) and with hospital outpatient departments to furnish care in the home (additional information is available on the next slide).

HHAs

- CMS clarified the applicability of the “home bound” requirement given the PHE and many public (e.g., state government determined) stay-at-home orders. [IFC 1]
- CMS clarified that during the PHE HHAs can use technology to supplement in-person care when documented in the plan of care. While virtual visits can’t replace certain in-person visits, they can be used to supplement them. [IFC 1]
- NPs, PAs, and other licensed health care practitioners can order *Medicaid* home health services (previously, only physicians could order) [IFC 1]
- HHAs can take up to 30 days to complete the comprehensive assessment, and do not need to submit OASIS data within 30 days – delayed submissions are permitted during the PHE. [WAIVER]
- HHAs can perform Medicare-covered initial assessments and determine patients’ homebound status remotely or by record review. [WAIVER]
- HHA nurses do not need to conduct on-site visit every two weeks. [WAIVER]
- Occupational Therapists can perform initial and comprehensive assessment for all patients, regardless of whether occupational therapy is the service that establishes eligibility, [WAIVER]
- HHAs can request accelerated payments for home health episodes that have not completed yet. MACs can auto-cancel these requests after a brief period of time, but CMS is allowing them to extend these cancellations in light of the PHE since it may take the HHAs longer to submit their claims. [WAIVER]
- CMS is working to implement Section 3708 of the Cares Act which will allow NP, PAs, Certified Nurse Midwives, and Clinical Nurse Specialists as practitioners who can certify home bound status and order home health in Medicare.
- CMS is also evaluating whether additional rulemaking is needed to implement Section 3707 of the Cares Act which allows additional use of technology for home health during the PHE (policy at least partially addressed in IFC 1).

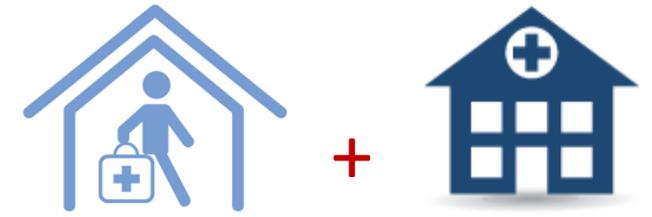
CMS Example Scenarios: Patient's Home & Home Health Agencies (HHAs)



Patients Home

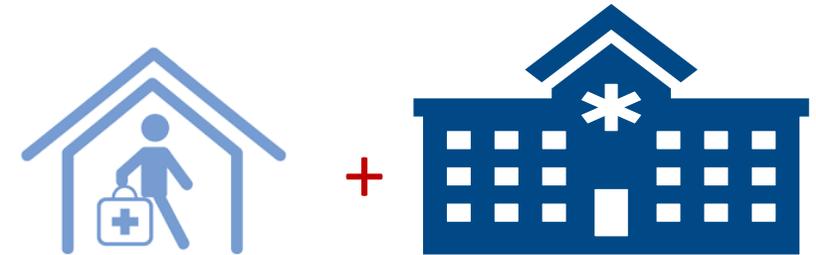
HHAs

HHAs can furnish care in the beneficiaries home during the PHE. In-person care can be supplemented by virtual care. Under the CARES Act, implemented via CMS' second IFC, NPs, clinical nurse specialists, PAs, and certified nurse midwives can now certify homebound status and order home health services.



HHAs + Physician Practice

HHAs can work under auxiliary personnel arrangements with physician practices. For example, HHAs could work with a physician to infuse chemotherapy in the patient's home. Under this scenario, a physician would be required to supervise the home health nurse (can use audio/video technology) and would bill for covered professional services under the physician fee schedule. The physician practice would pay the HHA directly.



HHAs + Hospital Outpatient (OPDs)

HHAs can partner with hospital outpatient departments to furnish covered hospital items and services in the home. The hospital's clinical staff would need to supervise the home health nurse (can use audio/video technology) and would bill for the services under the outpatient prospective payment system. The hospital would pay the HHA directly.

