COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing

Public Health Emergency (PHE) 1135 Waivers: Updated Guidance for Providers

On February 9, 2023, the Department of Health and Human Services (HHS) announced its intent to end the Public Health Emergency (PHE) for COVID-19 on May, 11, 2023. COVID-19 remains a significant priority for the Biden-Harris Administration and the Centers for Medicare & Medicaid Services (CMS) will work to ensure a smooth transition. During the PHE, CMS has used a combination of emergency authority waivers, regulations, enforcement discretion, and sub-regulatory guidance to ensure and expand access to care and to give health care providers the flexibilities needed to help keep people safe.

Some of the flexibilities that were created during the pandemic were recently expanded by the Consolidated Appropriations Act, 2023. Others, while critical to our response to COVID-19, are no longer needed. CMS has made further updates to our CMS Emergencies Page with useful information for providers – specifically around major telehealth and individual waivers – that were initiated during the PHE.

Please reference the following guidance in response to HHS's intent to end the PHE on May 11, 2023:
Provider-specific fact sheets about COVID-19 PHE waivers and flexibilities:
https://www.cms.gov/coronavirus-waivers

The FAQs in this document will sunset at the end of the COVID PHE and will not be updated. For future emergency and disasters; providers and suppliers should refer to the Medicare FFS PHE FAQs located at:

- With 1135 Waiver FAQs - https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf
- Without 1135 Waiver FAQs - https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_QsAs.pdf

We note that in many instances, the general statements of the FFS PHE FAQs referenced above have been superseded by COVID-19-specific legislation, emergency rules, and waivers granted under section 1135 of the Act specifically to address the COVID-19 PHE. The policies set out in this FAQ document are effective for the duration of the PHE unless superseded by previous direction or future legislation.

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A. Payment for Specimen Collection for Purposes of COVID-19 Testing

1. **Question:** What changes did CMS announce regarding specimen collection fees for COVID-19 testing?
   Answer: As part of the Public Health Emergency (PHE) for the COVID-19 pandemic and in an effort to be as expansive as possible within the current authorities to have diagnostic testing available to Medicare beneficiaries who need it, in the interim final rule with comment period, we are changing the Medicare payment rules during the PHE for the COVID-19 pandemic to provide payment to independent laboratories for specimen collection from beneficiaries who are homebound or inpatients not in a hospital for COVID-19 testing under certain circumstances.
   New: 4/9/20

2. **Question:** What has been the Medicare payment policy for specimen collection for laboratory testing and for transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital)?
   Answer: In general, the Social Security Act (the Act) requires that the Secretary establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses (generally referred to as a travel allowance) for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). The travel allowance is paid only when the nominal specimen collection is also payable. Refer to IOM, Pub. 100-04, Chapter 16, Section 60 for more information. For beneficiaries, neither the annual cash deductible nor the 20 percent coinsurance apply to the specimen collection fees or travel allowance for laboratory tests.
   New: 4/9/20

3. **Question:** How is the IFC changing the Medicare specimen collection and travel allowance policy?
   Answer: This IFC is providing a specimen collection fee and fees for transportation and personnel expenses known as a travel allowance for COVID-19 testing under certain circumstances for the duration of the PHE for the COVID-19 pandemic. The IFC also describes the definition of “homebound” for purposes of our specimen collection policy and allowing for electronic records of mileage for the travel allowance for the duration of the PHE for the COVID-19 pandemic.
   New: 4/9/20

4. **Question:** Who can bill for the Medicare specimen collection fee?
   Answer: Independent laboratories can bill Medicare through their MAC for the specimen collection fee. The specimen collection fee applies if the specimen is collected by trained laboratory personnel from a homebound or non-hospital inpatient and the specimen is a type that would not require only the services of a messenger pick up service. However, the specimen collection fee is not available for tests where a patient collects his or her own

specimen.
New: 4/9/20

5. **Question:** What is the nominal fee for specimen collection for COVID-19 testing for homebound and non-hospital inpatients during the PHE?
   Answer: The nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is $23.46 and for individuals in a non-covered stay in a SNF or whose samples are collected by a laboratory on behalf of an HHA is $25.46.
   Updated: 4/17/20

6. **Question:** What are the new level II HCPCS codes for specimen collection for COVID-19 testing?
   Answer: To identify specimen collection for COVID-19 testing, we established two new level II HCPCS codes effective March 1, 2020. Independent laboratories must use one of these HCPCS codes when billing Medicare for the nominal specimen collection fee for COVID-19 testing for the duration of the PHE for the COVID-19 pandemic. These HCPCS codes are:
   - G2023, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source
   - G2024, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source

   We note that G2024 is applicable to patients in a non-covered stay in a SNF and not to those residents in Medicare-covered stays (whose bundled lab tests would be covered instead under Part A's SNF benefit at §1861(h) of the Act).
   Updated: 4/17/20

7. **Question:** How should a laboratory document the miles traveled to collect a specimen?
   Answer: An independent laboratory billing Medicare for the travel allowance is required to log the miles traveled. CMS will not require paper documentation logs that some MACs may have otherwise required; electronic logs can be maintained instead. However, laboratories will need to be able to produce these electronic logs in a form and manner that can be shared with MACs.
   New: 4/9/20

8. **Question:** What is the definition of homebound for purposes of our specimen collection policy?
   Answer: Medicare beneficiaries are considered "confined to the home" (that is, "homebound") if it is medically contraindicated for the patient to leave the home. When it is medically contraindicated for a patient to leave the home, there exists a normal inability for an individual to leave home and leaving home safely would require a considerable and taxing effort.

As an example for the PHE for COVID-19 pandemic, this would apply for those patients: (1) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

A patient who is exercising "self-quarantine" for his or her own safety during a pandemic outbreak of an infectious disease, such as COVID-19, would not be considered "confined to the home" or "homebound" unless it is also medically contraindicated for the patient to leave the home. If a patient does not have a confirmed or suspected diagnosis of an infectious, pandemic disease such as COVID-19, but the patient's physician states that it is medically contraindicated for the patient to leave the home because the patient's condition may make the patient more susceptible to contracting an infectious, pandemic disease, the patient would be considered "confined to the home" or "homebound" for purposes of our specimen collection policy.
New: 4/9/20

B. Diagnostic Laboratory Services

1. **Question:** What are the general rules around how Medicare pays for clinical diagnostic laboratory tests?
   Answer: Medicare Part B, which includes a variety of outpatient services, covers medically necessary clinical diagnostic laboratory tests when a doctor or other practitioner orders them. Medically necessary clinical diagnostic laboratory tests are generally not subject to coinsurance or deductible.
   Updated: 12/11/20

2. **Question:** Are there Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes available for COVID-19 laboratory testing?
   Answer: Yes, CMS has created two HCPCS codes in response to the urgent need to bill for these services. The codes are:
   - U0001, CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and
   - U0002, 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC.

   Additionally, the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel has created CPT code 87635 (Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique) Please visit https://www.ama-assn.org/press-center/press-releases/new-cpt-code-announced-report-novel-coronavirus-

test
Laboratories can begin billing for the performance of these tests using these codes immediately via standard Fee-for-service billing practices.
Revised: 4/10/20

3. **Question:** Are all of these codes available for laboratories to use to bill Medicare?
   Answer: Yes. The CMS HCPCS codes will be available on the HCPCS and Clinical Laboratory Fee Schedule (CLFS) file beginning April 1, 2020, for dates of service on or after February 4, 2020. The AMA CPT code, 87635 will also be available on the HCPCS and CLFS file beginning April 1, 2020, for dates of service on or after March 13, 2020.
   Posted: 3/21/20

4. **Question:** My laboratory uses the CDC test kit; what code should we use to bill Medicare?
   Answer: The appropriate code to use would be HCPCS Code U0001 (CDC 2019-nCoV Real-Time RT-PCR) Diagnostic Panel).
   Posted: 3/21/20

5. **Question:** My laboratory does not use the CDC test kit; what code should we use to bill Medicare?
   Answer: If your laboratory uses the method specified by CPT 87635, the appropriate code to use would be CPT 87635. If your laboratory has a test that uses a method not described by CPT 87635, the appropriate code to use would be HCPCS Code U0002.
   Posted: 3/21/20

6. **Question:** What code should we use to bill Medicare if new types of COVID-19 tests are created in the future?
   Answer: The appropriate code to use would be HCPCS Code U0002 for COVID-19 test methods that are not specified by either U0001 or 87635. CMS will continue to monitor the types of COVID-19 testing methods and adjust coding as necessary depending on the methodology.
   Posted: 3/21/20

7. **Question:** How will Medicare pay for COVID-19 testing on the CLFS?
   Answer: Local MACs are responsible for developing the payment amount for claims they receive for these newly created HCPCS codes and the CPT code in their respective jurisdictions until Medicare establishes national payment rates on the CLFS. Please see https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf for more information on current MAC payment rates. If there are questions or concerns about payments, laboratories should contact their MAC with additional information.
   For more information on CMS's procedures for public consultation on payment for new clinical diagnostic laboratory tests on the CLFS, please see

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.
Revised 4/1/20

8. **Question:** My laboratory does not use the CDC test kit and will have a delay in implementing the CPT code 87635 in our billing system. May we bill Medicare using U0002?
Answer: Yes. For the time being laboratories may continue to use U0002 to bill Medicare for tests described by the CPT code. We will provide advance notice if this changes.
Posted: 3/21/20

9. **Question:** How has Medicare changed the requirements for clinical diagnostic laboratory testing during the PHE for COVID-19?
Answer: As part of the Interim Final Rule with Comment (IFC) published in the May 8, 2020 Federal Register, CMS removed, for the duration of the PHE for COVID-19, the requirement that the clinical diagnostic laboratory tests for COVID-19 and certain related viruses must be ordered by a treating physician or non-physician practitioner (NPP) who uses the tests in the management of the patient's specific medical problem. Medicare also removed certain documentation and recordkeeping requirements associated with orders for these COVID-19 and related clinical diagnostic laboratory tests, as these requirements would not be relevant in the absence of a treating physician's or NPP's order.

   As part of the IFC published in the September 2, 2020 Federal Register, CMS revised this policy by specifying that each beneficiary may receive Medicare coverage for one COVID-19 and related test without the order of a physician or other health **practitioner**, but Medicare will require such an order to cover further COVID-19 and related tests. We believe that broad COVID-19 testing without the order of any healthcare professional—including testing for the related conditions identified in the May 8th COVID-19 IFC—may result in a beneficiary not receiving the medical attention and oversight required to ensure that diagnosis and treatment is applied consistent with CDC guidelines and other medical standards. Therefore, this policy change helps ensure that beneficiaries receive appropriate medical attention, especially if they need multiple tests. It is also designed to stop fraudsters from performing or billing for unnecessary tests. In addition, to help ensure that beneficiaries have broad access to testing, CMS will also pay for tests when ordered by a pharmacist or other healthcare professional authorized under applicable state law to order diagnostic laboratory tests. Medicare makes payment for services of pharmacists and certain other healthcare professionals only when they have an arrangement with a physician or other billing practitioner. These changes allow Medicare to continue to pay for these tests during the PHE when they are ordered by pharmacists and other healthcare professionals without such an arrangement.

   The list of codes for which these ordering requirements apply can be found at

https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf. This list does not indicate coverage. Practitioners and laboratories should check with their local Medicare Administrative Contractor regarding specific questions of coverage.
Updated: 12/11/20

10. **Question:** Will Medicare keep requiring an order from a treating physician or NPP for flu or other tests?
Answer: Because the symptoms for influenza and COVID-19 might present in the same way, during the PHE each beneficiary may receive Medicare coverage for one COVID-19 and related test without the order of a physician or other health **practitioner when these tests are furnished in conjunction with a COVID-19 clinical diagnostic test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis.** Medicare will require, for coverage purposes, an order for all further COVID-19 and related tests, in accordance with the guidance in FAQ B9. The list of codes for which these ordering requirements apply can be found at https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf. This list does not indicate coverage. Practitioners and laboratories should check with their local Medicare Administrative Contractor regarding specific questions of coverage.
Updated: 12/11/20

11. **Question:** Does the CMS table "COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order during the PHE" list clinical diagnostic laboratory test codes that Medicare will cover during the PHE?
Answer: This table lists codes that, if otherwise covered by Medicare, do not require a treating practitioner's order as a condition of Medicare payment for the initial test and, for subsequent tests, can be ordered by a pharmacist or other healthcare professional authorized under applicable state law to order diagnostic laboratory tests. The table should not be interpreted as a statement of coverage for the listed codes. There may be some codes for which there are local coverage determinations that non-cover or limit coverage of certain tests. Practitioners and laboratories should check with their local Medicare Administrative Contractor regarding specific questions of coverage.
Updated: 12/11/20

12. **Question:** Please explain the different codes for use in COVID-19 specimen collection?
Answer: Medicare established two codes, G2023 and G2024, for specimen collection for COVID-19 clinical diagnostic laboratory tests. Independent clinical diagnostic laboratories can bill for these services as well as a travel allowance (HCPCS codes P9603 and P9604) when they collect specimens from beneficiaries who are homebound or non-hospital (SNF) Part B inpatients, that is, individuals in a Part B SNF stay and individuals whose samples will be collected by a laboratory on behalf of an HHA. However, these specimen collection fee codes may not be billed for a hospital or SNF inpatient in a Part A stay, as the costs for tests

(including sample collection) for those patients are already paid and covered as part of the stay. Please refer to IFC1 and the related FAQs, https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

Medicare is also paying for specimen collection by hospital outpatient departments and physician offices at their locations. Hospital outpatient departments can use new HCPCS code C9803 to bill for a clinic visit dedicated to specimen collection. This service is conditionally packaged and only receives separate payment when it is billed without another primary covered hospital outpatient service or with a clinical diagnostic laboratory test that is assigned status indicator "A" in Addendum B of the OPPS. Physician offices can use CPT code 99211 when office clinical staff furnish assessment of symptoms and specimen collection incident to the billing professionals services for both new and established patients. When the specimen collection is performed as part of another service or procedure, such as a higher-level visit furnished by the billing practitioner, that higher-level visit code should be billed and the specimen collection would not be separately payable. Physicians can bill for services provided by pharmacist's incident to their professional services consistent with requirements under 42 CFR 410.26 and state scope of practice and license requirements. The specimen collection codes (which do not include CPT code 99211) are only active during the PHE.
New 6/19/20

13. **Question:** If a COVID-19 diagnostic laboratory test is performed prior to a procedure in an HOPD, ASC or office, is it included as part of the procedure?
Answer: Currently, under the hospital OPPS all available COVID-19 clinical diagnostic laboratory tests are paid separately, thus, if a COVID-19 clinical diagnostic laboratory test is performed prior to a procedure and billed separately, it is not bundled into the payment for the procedure. Specifically, with regard to the hospital setting, if the hospital is billing for specimen collection for the COVID-19 clinical diagnostic laboratory test along with another hospital service, the payment for the specimen collection would be packaged into that of the procedure. If the ASC or physician office has obtained a CLIA certificate, the ASC (enrolled as a laboratory) or physician/Non physician-practitioner office can bill for tests under the clinical laboratory fee schedule (CLFS) that the certificate permits them to perform, separate from billing for the procedure that is being furnished. Practitioners, ASCs, and labs should check with their local Medicare Administrative Contractor regarding specific questions of coverage.
New 6/19/20

14. **Question:** If a physician/non-physician practitioner (NPP) reports CPT code 99211 "Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician", for assessment and collection of COVID-19 diagnostic laboratory test specimen for a new patient as permitted under Medicare during

the COVID-19 PHE, and the physician/Non-physician practitioner (NPP) subsequently, on a different day, furnishes an Evaluation and Management (E/M) visit to the patient for other reasons, can he/she report a new patient E/M visit code for the subsequent visit?
Answer: Yes, in this situation, under the unique circumstances of the PHE, the patient is not considered an established patient merely due to the reporting of CPT code 99211 for assessment and collection of COVID-19 specimen for a new patient. We note that if a higher level E/M visit is furnished to a new patient at the time of COVID-19 specimen collection, the encounter should be reported using the higher level new patient visit code rather than CPT code 99211, and in this case the patient would be considered an established patient for the subsequent visit and a new patient E/M visit code should not be reported until 3 years have passed, as specified under the usual billing rules.
New: 7/28/20

15. **Question:** Can physicians/NPPs apply the Cost Sharing (CS) modifier to claims for pre-surgery examination services that include COVID-19 testing?
Answer: The CS modifier should not be used when pre-surgery examination services are not paid separately, for example if particular services are considered to be part of services with a global surgical period, End Stage Renal Disease (ESRD) services with a monthly capitation payment or maternity package services.

During the COVID-19 PHE, the modifier can be reported with separately reported visit codes that result in an order for or administration of a COVID-19 test, when they are related to furnishing or administering such a test or are for the evaluation of an individual for purposes of determining the need for such a test.
New: 7/28/20

16. **Question:** Does Medicare cover COVID-19 testing solely for the purposes of travel?
Answer: No. In general, for people covered by original fee-for-service Medicare, Medicare pays for COVID-19 diagnostic tests performed by a laboratory, such as PCR and antigen tests, with no beneficiary cost sharing when the test is ordered by a physician, non-physician practitioner, pharmacist, or other authorized health care professional who uses the results in the management of the beneficiary's specific medical problem. In the April 2020 Interim Final Rule (CMS-5531-IFC) , CMS established Medicare coverage on an interim basis of FDA-authorized COVID-19 serology tests for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. During the PHE, people with Medicare can access one laboratory performed test without cost sharing without an order. For individuals who do not meet the coverage requirements set forth in CMS-5531-IFC and are seeking COVID testing performed by a laboratory solely for the purpose of travel, a COVID test would not be covered. As a reminder, people with Medicare Part B can also receive up to eight over-the-counter COVID-19 tests per calendar month from participating pharmacies and health care providers through an initiative

announced in April 2022.
New: 8/16/22

17. **Question:** Is it appropriate for a clinical laboratory to bill and accept cash payments from Medicare Part B beneficiaries for COVID-19 testing solely for the purposes of travel?
Answer: Providers and suppliers are required to submit claims for Medicare-covered services (see *section 1848(g)(4) of the Social Security Act*). However, in general, if a service is not covered by Medicare because it is not within the scope of a Medicare benefit, providers and suppliers may bill and accept direct payments from beneficiaries for those services. CMS strongly encourages providers and suppliers to issue an advance beneficiary notice of noncoverage (ABN) for care that is never covered because it does not meet the definition of a Medicare benefit, including COVID-19 testing performed solely for the purposes of travel (see CMS IOM Pub. 100-04 Medicare Claims Processing Manual, Chapter 30, section 50.2.1). Providers and suppliers are reminded if a beneficiary requests they submit a claim for a service Medicare never covers because it isn't a Medicare benefit, the GX and GY modifiers must be used as described in MLN Booklet Medicare Advance Written Notices of Non-coverage.
New: 8/16/22

C. Diagnostic Laboratory Services - Serology Testing

1. **Question:** Are there new Current Procedural Terminology (CPT) codes for COVID-19 testing?
Answer: On April 10, 2020, the American Medical Association (AMA) CPT Committee announced two new CPT codes to report when patients receive blood tests that can detect antibodies for COVID-19. These two codes are:
    - 86328: Immunoassay for infectious agent antibody(ies), qualitative or semi-quantitative, single step method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
    - 86769: Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

    New: 5/1/20

2. **Question:** When will I be able to bill Medicare for these new test codes?
Answer: Medicare has updated its billing systems to accept these new test codes.
New: 5/1/20

3. **Question:** My laboratory has a serology test for COVID-19; which CPT code should I use to bill Medicare?
Answer: Both new test codes can be used to bill Medicare for COVID-19 serology testing that can detect antibodies. If your COVID-19 test can be done in a single step, the most appropriate code to use is 86328. Multi-step antibody testing for COVID-19 can be billed using 86769.

New: 5/1/20

4. **Question:** What is the difference between single-step and multi-step antibody test for COVID-19?
   Answer: According to the AMA, CPT code 86328 was established for antibody tests using a single-step method immunoassay. This testing method typically includes a strip with all of the critical components for the assay and is appropriate for a point of care platform. CPT code 86769 was established for COVID-19 antibody tests using a multiple step method. This testing method often involves several steps where a diluted sample is incubated in a sample plate.
   New: 5/1/20

5. **Question:** How is the Medicare payment amount determined for the new COVID-19 CPT codes?
   Answer: Local MACs are responsible for developing the payment amount for claims they receive for these newly created CPT codes in their respective jurisdictions until Medicare establishes national payment rates on the CLFS. Please see https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf for more information on current MAC payment rates. If there are questions or concerns about payments, laboratories should contact their MAC for additional information. For more information on CMS's procedures for public consultation on payment for new clinical diagnostic laboratory tests on the CLFS, please see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.
   New: 5/1/20

6. **Question:** Can I continue to use HCPCS code U0002 to bill Medicare for COVID-19 testing?
   Answer: Yes, HCPCS code U0002 is still available for billing Medicare if your test does not fit any of the other existing code descriptors for COVID-19 testing.
   New: 5/1/20

D. High Throughput COVID-19 Testing

1. **Question**: Why did CMS create HCPCS codes U0003, U0004 and U0005?
   Answer: CMS created two new HCPCS codes, effective for dates of service on or after April 14, 2020, specifically for Clinical Diagnostic Laboratory Tests (CDLTs) making use of high throughput technologies, that is, technologies that use a platform that employs automated processing of more than 200 specimens a day, as described in CMS Ruling No. CMS-2020-1-R, available at https://www.cms.gov/files/document/cms-2020-01-r.pdf.

   These new HCPCS codes are:
   - U0003: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID19]),

amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R

- U0004: 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R

  On October 15, 2020, CMS released an amended Ruling (CMS 2020-1-R2) that created an add-on payment for COVID-19 CDLTs performed using high throughput technology (as described by HCPCS codes U0003 and U0004). This add-on payment can be billed using HCPCS code U0005 effective January 1, 2021, and is described as follows:

- U0005: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within two calendar days from date and time of specimen collection. (List separately in addition to either HCPCS code U0003 or U0004)

  Effective date: U0003 and U0004 were effective for dates of service on or after April 14, 2020. U0005 is effective January 1, 2021.
  New: 10/16/2020

2. **Question**: What will Medicare FFS pay for HCPCS codes U0003, U0004 and U0005?
   Answer: The Administrative Ruling CMS 2020-1-R2, which amends the April 14 Administrative Ruling, establishes that HCPCS codes U0003 and U0004 will be paid at rate of $75. When the code becomes effective on January 1, 2021, the add-on payment described by HCPCS code U0005 will be paid at a rate of $25. HCPCS code U0005 should be billed on the same claim as either HCPCS codes U0003 or U0004 when appropriate.

   Effective Date: Payment amounts for HCPCS codes U0003 and U0004 will be changed to $75 on January 1, 2021. HCPCS code U0005 is effective January 1, 2021 and will have a payment rate of $25.
   New: 10/16/2020

3. **Question**: When can HCPCS codes U0003, U0004 and U0005 be billed to Medicare?
   Answer: The effective date of CMS Ruling 2020-01-R is April 14, 2020. The $100 Medicare payment rates for HCPCS codes U0003 and U0004 apply to CDLTs with dates of service between April 14, 2020 and December 31, 2020. The effective date of CMS Ruling 2020-1-R2 is January 1, 2021. Starting on that date and until the end of the Public Health Emergency, the payment rate for HCPCS codes U0003 and U0004 will be $75. In addition, starting January 1, 2021, the payment rate for HCPCS code U0005 will be $25.

Effective date: See answer
New: 10/16/2020

4. **Question:** What is the definition of high throughput technology under the new Administrative Ruling CMS 2020-1-R2?
   Answer: Administrative Ruling CMS 2020-1-R2 uses the same definition for high throughput technology used in April 14, 2020 Administrative Ruling CMS 2020-1-R1. The April 14 Ruling states: "A high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day."

   Effective date: CMS 2020-1-R2 is effective January 1, 2021.
   New: 10/16/2020

5. **Question**: My laboratory testing platform is not specifically listed in CMS Ruling CMS-2020-01-R. Can my laboratory bill Medicare for tests run on my platform using U0003 and U0004?
   Answer: Laboratories may bill Medicare HCPCS codes U0003 and U0004 when the tests described in those codes make "use of high throughput technologies as described by CMS-2020-01-R." The Ruling includes a list of examples of high throughput technology as of April 14, 2020, and states that high throughput technologies are not limited to technologies listed in the Ruling. The Ruling states: "A high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day." Laboratories should ensure that the technologies they are using meet this definition when they bill Medicare using these codes.

   Effective date: HCPCS codes U0003 and U0004 are effective as of April 14, 2020.
   New: 10/16/20

6. **Question**: What payment changes is Medicare making to COVID-19 CDLTs performed using high throughput technology?
   Answer: Through an April 14, 2020 Ruling (CMS-2020-1-R), CMS established two new HCPCS codes (U0003 and U0004) to describe COVID-19 CDLTs performing using high throughput technology and established a payment rate of $100 for both codes.

   Under the amended Administrative Ruling (CMS-2020-1-R2), CMS will lower the base payment amount for both HCPCS codes to $75, effective January 1, 2021. CMS will make an additional $25 add-on payment to laboratories if they meet the following two requirements to bill for HCPCS code U0005: a) they completed the COVID-19 CDLT in 2 calendar days or less from the date of specimen collection, and b) the majority of their COVID-19 CDLTs performed using high throughput technology in the previous calendar month were completed in 2 calendar days or less for all of their patients (not just their Medicare patients). As a result, laboratories that complete these CDLTs within 2 days of the date the

specimen is collected may bill for HCPCS code U0005 and will be paid $100 while laboratories that take longer will receive a $75 payment.

Effective date: CMS 2020-1-R2 is effective January 1, 2021.
New: 10/16/2020

7. **Question:** Will laboratories have to bill differently compared with the direction provided in the April 14, 2020 ruling?
Answer: Through an April 14, 2020 Ruling (CMS-2020-1-R), CMS established two new HCPCS codes (U0003 and U0004) to describe COVID-19 CDLTs performed using high throughput technology. Laboratories should continue to use these same codes where appropriate to describe the CDLTs they are performing. However, effective January 1, 2021, laboratories can also bill Medicare for a $25 add-on payment using HCPCS code U0005 if: a) they completed the COVID-19 CDLT in 2 calendar days or less from the date of specimen collection, and b) the majority of their COVID-19 CDLTs performed using high throughput technology in the previous calendar month were completed in 2 calendar days or less for all of their patients (not just their Medicare patients).

   Effective date: CMS 2020-1-R2 is effective January 1, 2021.
   New: 10/16/2020

8. **Question:** CMS has indicated that laboratories must complete the test within two calendar days of the date the specimen is collected. What does it mean to "complete" the lab test?
Answer: Per CMS 2020-1-R2, CMS considers the test to be "complete" when the results of the test are finalized and ready for release.

   Effective date: CMS 2020-1-R2 is effective January 1, 2021.
   New: 10/16/2020

9. **Question:** What requirements do laboratories have to meet to bill the new $25 add-on payment for COVID-19 diagnostic tests run on high throughput technology?
Answer: Starting January 1, 2021, laboratories can bill Medicare for the $25 add-on payment using HCPCS code U0005 if:
   1) they completed the COVID-19 CDLT in 2 calendar days or less from the date of specimen collection; and
   2) the majority of their COVID-19 CDLTs performed using high-throughput technology in the previous calendar month were completed in two calendar days or less for all of their patients (not just their Medicare patients).

      CMS has provided additional information in CMS-2020-1-R2 regarding how laboratories would demonstrate their CDLT timeliness for all of their patients in the event of an audit

or other CMS oversight activity.

Effective Date: CMS 2020-1-R2 is effective January 1, 2021.
New: 10/16/2020

10. **Question:** CMS has indicated that in order to bill HCPCS code U0005 the majority of a laboratory's COVID-19 CDLTs performed using high throughput technology in the previous calendar month were completed in 2 calendar days or less for all of their patients (not just their Medicare patients). How would a laboratory demonstrate compliance with this requirement? Over what time period would a laboratory calculate their COVID-19 CDLT test timeliness?
Answer: Laboratories would assess their COVID-19 CDLT timeliness in the month preceding the month identified by the line date of service for the corresponding CDLT represented by HCPCS code U0003 or U0004. In the circumstance that the laboratory has not completed 51% of CDLTs for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (for all patients) in 2 calendar days from the date the specimen was collected during the applicable month, then it may not bill for HCPCS code U0005 with either HCPCS code U0003 or U0004.

    For example, a laboratory is submitting a claim to Medicare for a CDLT performed on high throughput technology for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 using HCPCS code U0003 with a line date of service of May 15, 2021. The laboratory would assess its performance based on those CDLTs completed during the calendar month (April 1, 2021 – April 30, 2021) that precedes the month identified by the CDLT line date of service (May 2021). If the laboratory completed a total of 1000 of the same CDLTs using high throughput technology (including all tests from non-Medicare patients) in April, and 490 had been completed within 2 calendar days of the specimen being collected, the laboratory would have a 49% test timeliness completion rate and may not bill for the $25 add-on payment as represented by HCPCS code U0005.

    Effective date: CMS 2020-1-R2 is effective January 1, 2021.
    New: 10/16/2020

11. **Question:** CMS has indicated that in order to bill Medicare for HCPCS code U0005 the majority of a laboratory's COVID-19 CDLTs performed using high throughput technology in the previous calendar month must have been completed in 2 calendar days or less from the date of specimen collection for all of their patients (not just their Medicare patients). What does "majority" mean in this context?
Answer: For purposes of CMS Ruling No. CMS 2020-1-R2, https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf, "majority" means 51% or greater.

We note that the requirement that the majority of a laboratory's COVID-19 CDLTs performed using high throughput technology in the previous calendar month must have been completed in two calendar days or less from the date of specimen collection pertains to the laboratory's ability to bill Medicare for the $25 add-on payment using HCPCS code U0005. Laboratories may continue to bill Medicare for COVID-19 CDLTs making use of high throughput technology described by HCPCS codes U0003 and U0004, regardless of whether they meet this requirement.
Effective date: CMS 2020-1-R2 is effective January 1, 2021.
New: 12/16/20

12. **Question:** Can a laboratory submit a claim for HCPCS code U0005 (the add-on payment) by itself, or does U0005 need to be reported with either HCPCS code U0003 or U0004 (CDLTs for COVID-19 performed using high throughput technology)?
Answer: As required by the HCPCS code U0005 code descriptor, laboratories must report HCPCS code U0005 on the same claim as either HCPCS code U0003 or U0004.
Effective date: CMS 2020-1-R2 is effective January 1, 2021.
New: 12/16/20

13. **Question:** CMS Ruling No. CMS 2020-1-R2 states that for a laboratory to be able to bill Medicare for HCPCS code U0005, the test described by HCPCS code U0003 or U0004 must be completed in 2 calendar days. Please clarify when the 2-calendar day timeframe begins and ends.
Answer: Beginning with dates of service on or after January 1, 2021, laboratories can bill Medicare for the $25 add-on payment using HCPCS code U0005 when: 1) they completed the COVID-19 CDLT in 2 calendar days or less from the date of specimen collection; and 2) the majority of their COVID-19 CDLTs performed using high throughput technology in the previous calendar month were completed in 2 calendar days or less for all of their patients (not just their Medicare patients). For example, if the specimen is collected anytime Wednesday then the COVID-19 CDLT would need to be completed, that is, results are finalized and ready for release, by 11:59PM Friday. In other words, the specimen collection day (Wednesday) is day 0, Thursday is day 1, and Friday is day 2.
Effective date: CMS 2020-1-R2 is effective January 1, 2021.
New: 12/16/20

E. Hospital Services

1. **Question:** During the COVID-19 PHE, can my hospital provide inpatient services at a site (temporary expansion site) that is not currently part of the hospital or even of another type of existing healthcare facility? For example, if local hospitals are almost at capacity during the emergency and the few beds remaining must be reserved for patients needing ventilators and critical care, will Medicare pay for non-critical care inpatient services

provided directly by the hospital at a temporary expansion site, such as a repurposed school gymnasium or erected tent?
Answer: During the COVID-19 PHE, CMS is allowing hospitals to provide inpatient hospital services in temporary expansion sites, which may include ambulatory surgical centers (ASCs), repurposed gymnasiums, erected tents, or other sites, to help address the urgent need to expand their care capacity and to develop COVID-19 specific treatment sites. If a hospital meets the CoPs in effect during the COVID-19 PHE while operating one or more temporary expansion sites, Medicare will pay for covered Medicare inpatient services provided at those sites as if they were provided at the permanent inpatient locations of the hospital. If services were provided by the hospital in another Medicare-participating facility, that facility would not bill Medicare for items and services provided by the hospital. The hospital is expected to be operating in a manner not inconsistent with its state's emergency preparedness or pandemic plan.
New: 5/1/20

2. **Question**: During the COVID-19 PHE, can my hospital provide outpatient services at a site (temporary expansion site) not considered part of the hospital or even of an existing healthcare facility? For example, if my hospital needs to set up temporary sites for testing or treatment of patients, including those who are COVID-19 positive or suspected to be positive who may need to be isolated, can my hospital provide outpatient services at such a temporary site?
   Answer: Similar to what CMS is allowing for hospital inpatient services (described above), during the COVID-19 PHE, CMS is allowing hospitals to provide hospital outpatient services in temporary expansion sites, which may include ASCs, gymnasiums or other sites, to help address the urgent need to expand their care capacity. If a hospital meets the CoPs in effect during the COVID-19 PHE while operating one or more temporary expansion sites, Medicare will pay for covered Medicare outpatient services provided at those sites as if they were provided at the permanent outpatient locations of the hospital. The hospital is expected to be operating in a manner not inconsistent with its state's emergency preparedness or pandemic plan.
   Revised: 11/16/21

3. **Question:** Can an acute care hospital repurpose areas of the hospital that are not currently used for patient care (e.g., a cafeteria) as patient care areas, or existing areas that are used for patient care (e.g., outpatient beds) as higher level care areas (e.g., inpatient acute care beds) during the Public Health Emergency?
   Answer: CMS is providing needed flexibility to hospitals to ensure they have the ability to expand capacity and to treat patients during the COVID-19 PHE. As part of the *CMS Hospital Without Walls* initiative, for the duration of the COVID-19 PHE, hospitals can repurpose existing clinical (e.g., outpatient beds) and non-clinical space (e.g., cafeterias) for use as acute inpatient patient care areas to help address the urgent need to increase capacity.

New: 4/9/20

4. **Question**: How can Ambulatory Surgical Centers (ASCs) address the needs of patients who may need hospital or ambulatory care during the COVID-19 Pandemic Public Health Emergency?
   Answer: During the PHE, ASCs may help address the needs in surge areas in several ways. An ASC may furnish inpatient services under arrangement for a hospital, or become provider-based to a hospital, or choose to enroll as a hospital themselves. If an ASC is enrolled as a hospital, they must meet the hospital Conditions of Participation, to the extent not waived, and may provide any hospital inpatient or outpatient service provided that it operates in a manner not inconsistent with the State's emergency preparedness or pandemic plan (for example: COVID-19 treatment site). The ASC would be, functioning as a full hospital, not solely as a hospital outpatient surgical department. Under any of these scenarios, these entities may provide any hospital service as they would be functioning as a hospital rather than an ASC. ASCs that do not provide hospital services under arrangements to an existing hospital or that do not enroll as a hospital themselves may furnish only those services on the ASC Covered Procedures List.
   Revised: 11/16/21

5. **Question:** Do hospitals need to report to CMS or the Medicare Administrative Contractor that they have repurposed an existing area, or worked with an off-site location to create new outpatient or inpatient space?
   Answer: No. If the Medicare-approved hospital intends to bill Medicare for the services provided under arrangement, no additional enrollment actions are required. Hospitals may begin billing for care in their surge locations or expansion site for inpatient or outpatient services under their existing CMS Certification Number (CCN) for care furnished during the PHE. CMS will also be exercising our enforcement discretion and will not be conducting the onsite survey for hospital surge locations during the PHE.
   New: 4/9/20

6. **Question:** Where can I find the specific waivers to the Medicare Conditions of Participation for acute care and critical access hospitals as well as waivers to the provider-based billing rules?
   Answer: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf
   New: 4/9/20

7. **Question:** Will an ASC that chose to convert its enrollment to a hospital during the PHE be required to file a Medicare cost report?
   Answer: For the duration of the PHE, ASCs which rely on blanket waivers issued by CMS to enroll as hospitals during the time period of the PHE will be deemed to have low Medicare

program utilization under 42 CFR 413.24(h) and will not be required to submit a full Medicare cost report. These providers will be deemed to satisfy the Medicare cost report submission requirements under 42 CFR 413.24(h) by submitting reduced cost report to their contractors consisting only of a completed and signed certification page from the hospital cost report (Form CMS-2552-10, Worksheet S), signed by the Chief Financial Officer or Administrator.

Payments such hospitals receive from the Medicare Inpatient Prospective Payment System or Outpatient Prospective Payment System will be considered as payment in full. Their cost reports will not be used for reconciliation for any additional payments such as disproportionate share, uncompensated care, direct graduate medical education, or Medicare bad debt. Additionally, the cost report data will not be collected and included in the wage index calculations. The Surge Capacity Hospitals' Medicare cost reports will be due on or before the last day of the fifth month following the close of their fiscal year end, pursuant to §413.24(f)(2), and electronic filing requirements are waived.
New: 4/9/20

8. **Question:** Can an acute care hospital work with another entity to do patient testing offsite, such as in a parking lot?
   Answer: Yes. Under existing law and regulations, a hospital may elect to furnish hospital outpatient diagnostic tests under arrangements with another entity. The hospital bills Medicare for these services under this scenario. In addition, as mentioned above, the hospital itself may repurpose clinical or non-clinical sites for hospital outpatient or inpatient care under the flexibilities adopted for the duration of the PHE.
   New: 4/9/20

9. **Question:** The state government, U.S. Army Corps of Engineers, or other governmental entity established a new care location in our area by repurposing and retrofitting a convention center, gymnasium, tent or other site for patient care. Following its development, our hospital has been brought in to operate and staff this site with our clinicians. Can we bill Medicare for the facility and professional services our organization provides there? If so are there reporting or billing rules that determine how this is done?
   Answer: Medicare enrolled hospitals that assume the majority operations of a temporary expansion site – including gymnasiums, tents, convention centers, and others – that was built or retrofitted by a public entity can bill Medicare for covered inpatient and outpatient hospital services provided to Medicare beneficiaries at those temporary expansion sites. These temporary expansion sites need to meet the refined hospital conditions of participation. Hospitals would need to follow existing rules to bill under the applicable Medicare payment system depending on whether they provided outpatient care or inpatient care. Hospitals should add the “DR” condition code to inpatient and outpatient claims for patients treated in temporary expansion site during the Public Health Emergency.

Similarly, practitioners that furnish covered professional services to Medicare beneficiaries in these temporary expansion sites can bill Medicare for these hospital services. Practitioners should use the applicable place of service code depending on whether the temporary expansion site is being used to furnish outpatient or inpatient care. Also, practitioners should add the modifier "CR" to professional claims for patients treated in temporary expansion site during the Public Health Emergency.
New: 4/9/20

10. **Question:** Will Medicare provide additional payment if a patient needs to be isolated or quarantined in a private room?
Answer: If a Medicare beneficiary is a hospital inpatient for medically necessary care and needs to be isolated or quarantined in a private room, Medicare will pay the Diagnostic Related Group (DRG) rate and any outlier costs for the entire stay until the Medicare patient is discharged. The DRG rate (and outlier payments as applicable) includes payment for when a patient needs to be isolated or quarantined in a private room.

    There also may be times when beneficiaries may need to be isolated or quarantined in a hospital private room to avoid infecting other individuals. These patients may not meet the need for acute inpatient care any longer, but may remain in the hospital for public health reasons.

    Hospitals having both private and semiprivate accommodations may not charge the patient a differential for a private room if the private room is medically necessary. Patients who would have been otherwise discharged from the hospital after an inpatient stay, but are instead remaining in the hospital under quarantine, would not have to pay an additional deductible for quarantine in a hospital.
    New: 4/9/20

11. **Question:** Can a provider that has both private and semiprivate accommodations charge the patient a differential for a private room where isolation of a beneficiary is required?
Answer: A provider with both private and semiprivate accommodations may not charge the patient a differential for a private room if the private room is medically necessary.
    Posted: 3/6/20

12. **Question:** Will a hospital be eligible for additional payment for rendering services to patients that remain in the hospital in the case where they continue to need medical care but at less than an acute level and those services are unavailable at any area skilled nursing facilities (SNFs) because of an emergency, including the COVID-19 infection?
Answer: A physician may certify or recertify the need for continued hospitalization if the physician finds that the patient could receive proper treatment in a SNF, but no bed is

available in a participating SNF. Assuming the original inpatient admission was appropriate for Part A payment, Medicare will pay the DRG rate and any outlier costs for the entire stay until the Medicare patient can be moved to an appropriate facility.
Posted: 3/6/20

13. **Question:** Are hospitals that are paid by Medicare through the Inpatient Prospective Payment System (IPPS) going to be paid using a special payment method during the COVID-19 emergency? Is there a special DRG rate at which IPPS hospitals will be reimbursed for this situation?
Answer: There is no special DRG for COVID-19. Recent legislation in the CARES Act provides for increased IPPS payments during the emergency period for Medicare inpatients diagnosed with COVID-19. Further guidance on the implementation of this increased IPPS payment is forthcoming. Otherwise, normal prospective payment methodologies apply to hospitals' discharges paid under the IPPS rate.
Posted: 3/6/20

14. **Question:** We have a Medicare psychiatric patient requiring inpatient psychiatric care who cannot be placed in the excluded distinct part psychiatric unit because of the COVID-19 emergency. Can we place the psychiatric patient in an acute care hospital bed?
Answer: Yes, an acute care hospital with an excluded distinct part psychiatric unit that, as a result of a disaster or emergency, needs to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed can relocate patients. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System for such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the emergency. This may occur where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.
Revised: 3/26/20

15. **Question:** Can acute care hospitals use inpatient rehabilitation unit beds to increase bed capacity as a result of the COVID-19 emergency?
Answer: Yes, CMS has issued a blanket waiver (https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf) to allow acute care hospitals to house inpatients in their excluded distinct part inpatient rehabilitation facility (IRF) units, where the IRF unit's beds are appropriate for acute care. The acute care hospital bills for the care under the Inpatient Prospective Payment System and annotates the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit related to the disaster or emergency.

Since these patients would be acute care patients housed in the IRF solely to meet the demands of an emergency, they would not be required to meet the Medicare coverage requirements for IRFs found in 42 CFR 412.622(a)(3), (4), and (5), and guidance in Chapter 1, Section 110 of the Medicare Benefit Policy Manual (Pub. 100-02) and would be excluded from the requirements specified in 42 CFR 412.29(b), which is the regulation commonly referred to as the "60 percent rule."
New: 3/26/20

16. **Question**: Are there any special waivers or exemptions that only apply to hospitals paid under TEFRA (e.g., IPPS-excluded cancer hospitals or children's hospitals)?
Answer: At this time there are no waivers or exemptions that only apply to hospitals paid under TEFRA. However, waivers that are generally applicable to hospitals regardless of hospital type are applicable to hospitals paid under TEFRA.
New: 5/27/20

17. **Question**: My hospital needs to transfer a patient to a temporary acute care location operated by the state, military or other public entity during the COVID-19 PHE. What are Medicare's billing and claim processing rules associated with these transfers?
Answer: Hospitals should refer to Medicare's claims processing manual for instructions on Medicare inpatient hospital billing: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf. A patient status code should be included on every Inpatient Prospective Payment System (IPPS) claim, which indicates the location where the patient was discharged or transferred. For example, code "01" indicates that the patient was discharged to home or self-care, and code "02" indicates that the patient was discharged or transferred to another acute care hospital.

    When patients have a short length of stay and are transferred to another acute care hospital, or in other certain circumstances, CMS may adjust payments to IPPS hospitals under the IPPS transfer policy. (See https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AcutePaymtSysfctsht.pdf for more information on the IPPS Transfer Policy and other adjustments to payments.)

    In March 2020, the National Uniform Billing Committee (NUBC), which maintains data elements and codes for Medicare's inpatient billing requirements, reminded stakeholders that patient status code "69 - Discharged/transferred to a designated disaster alternative care site" is applicable in these situations (see https://www.nubc.org/system/files/media/file/2020/03/ACS%20Announcement_v2.pdf). Medicare-enrolled hospitals that transfer a patient to a temporary care site operated by a public entity (e.g., the military) should use patient status code "69" on the Medicare inpatient claim. When a claim with patient status code "69" is processed, a transfer

adjustment is not calculated.
New: 5/27/20

Question: Is CMS giving any flexibility to teaching hospitals to meet the deadline of July 1 for submission of Medicare GME affiliation agreements?
Answer: Yes. Due to the COVID-19 PHE, instead of requiring that new Medicare GME affiliation agreements be submitted to CMS and the MACs by July 1, 2020 (for the academic year starting July 1, 2020), and that amendments to Medicare GME affiliation agreements be submitted to CMS and the MACs by June 30, 2020 (for the academic year ending June 30, 2020), CMS allowed hospitals to submit new and/or amended Medicare GME affiliation agreements as applicable to CMS and the MACs by January 1, 2021.

As a result of the continuation of the PHE effective April 21, 2021, CMS is once again extending the submission deadline for both new Medicare GME affiliation agreements and amendments of existing Medicare GME affiliation agreements. New Medicare GME affiliation agreements must be submitted by January 1, 2022 (for the academic year starting July 1, 2021) and amended Medicare GME affiliation agreements must be submitted by January 1, 2022 (for the academic year ending June 30, 2021).

Specifically, under current CMS regulations, two or more teaching hospitals may form a Medicare GME affiliated group to aggregate their direct graduate medical education (DGME) and/or indirect medical education (IME) resident caps and provide needed flexibility for purposes of cross-training residents. Medicare GME affiliated group is defined at 42 CFR 413.75(b) as:

1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in subpart D of Part 412 of this subchapter) or in a contiguous area and meet the rotation requirements in 42 CFR 413.79(f)(2).
2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in §413.79(f)(2), and are jointly listed
    i. As the sponsor, primary clinical site, or major participating institution for one or more programs as these terms are used in the most current publication of the Graduate Medical Education Directory; or
    ii. As the sponsor or is listed under “affiliations and outside rotations” for one or more programs in operation in Opportunities, Directory of Osteopathic Postdoctoral Education Programs.
3) Two or more hospitals that are under common ownership and, effective for all Medicare GME affiliation agreements beginning July 1, 2003, meet the rotation requirement in §413.79(f)(2).

Under 42 CFR 413.79(f)(1), each hospital in the Medicare GME affiliated group must submit the Medicare GME affiliation agreement to the CMS Central Office with a copy to the hospital’s MAC no later than July 1 of the residency program year during which the

Medicare GME affiliation agreement will be in effect. In addition, the May 12, 1998 Health Care Financing Administration Final Rule (63 FR 26318, 26339) states that "the hospitals in the affiliated group may adjust the initial FTE counts by June 30 of each residency training year if actual FTE counts for the program year are different than projected in the original agreement."

CMS believes that teaching hospitals need the flexibility to adjust the membership and the resident counts in Medicare GME affiliated groups during the COVID-19 PHE, as sites of care and patient needs quickly evolve. During the COVID-19 PHE, teaching hospitals are unsure of what the next several months will entail in terms of the need to deploy residents to alternate care sites, and what effect these decisions may have on their DGME and IME resident caps. It may also be administratively challenging during the COVID-19 PHE to arrange and enter into meaningful resident cap sharing arrangements among hospitals. Accordingly, due to the COVID-19 PHE, CMS is allowing hospitals to submit new and/or amended Medicare GME affiliation agreements as applicable to CMS and the MACs by January 1, 2022. As under existing procedures, hospitals should email new and/or amended agreements to CMS at Medicare_GME_Affiliation_Agreement@cms.hhs.gov, and indicate in the subject line whether the affiliation agreement is a new one or an amended one.
Revised: 5/24/20

18. **Question:** When submitting an extraordinary circumstances relocation request to the Regional Office, should the email be encrypted?
Answer: Yes.
New: 6/16/20

19. **Question:** Can hospitals bill for and receive separate payment for COVID-19 testing services that are provided in the outpatient department prior to an inpatient admission?
Answer: Generally, hospitals may not bill for and receive separate Medicare FFS payment for COVID-19 testing services on the day of inpatient admission, the day immediately preceding inpatient admission, and, for most hospitals, the two days prior to that. For subsection (d) hospitals (e.g., hospitals paid under the inpatient prospective payment system (IPPS), payment for clinical diagnostic tests provided by the hospital, or by an entity wholly owned or operated by the hospital, during the 3 days immediately preceding an inpatient admission is included in payment for the inpatient stay. In the case of a hospital that is not a subsection (d) hospital (e.g., hospitals excluded from the IPPS, such as LTCHs, inpatient rehabilitation facilities, inpatient psychiatric facilities, children's hospitals), payment for clinical diagnostic tests provided by the hospital, or by an entity wholly owned or operated by the hospital, during the 1 day immediately preceding an inpatient admission is included in the payment for the inpatient stay. These payment windows are required by section 1886(a)(4) of the Act. Critical Access Hospitals (CAHs) may bill and receive separate payment for COVID-19 testing services provided in the outpatient department prior to an

inpatient admission because they are not subject to the payment window policy described above. Please note that separate rules apply to the program for Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured (https://www.hrsa.gov/coviduninsuredclaim), which is administered by the Health Resources & Services Administration (HRSA).
New: 7/28/20

20. Question: CMS is waiving the entire utilization review (UR) condition of participation at 42 CFR 482.30, which requires that a hospital must have a UR committee with a UR plan that provides for review for Medicare and Medicaid patients with respect to the medical necessity of the admissions to the institution, duration of stays, and professional services furnished, including drugs and biologicals. Does that mean that the use of Condition Code 44 is waived as well?
Answer: No, Condition Code 44 still applies. Although CMS has waived the UR condition of participation at 42 CFR 482.30, this does not mean that if a beneficiary's status is changed from inpatient to outpatient and there is a determination that the inpatient admission does not meet the hospital's inpatient criteria, that the hospital may bill an inpatient claim. Hospitals should report Condition Code 44 as appropriate.
New: 8/7/20

21. Question: Under the CMS hospital Conditions of Participation (CoPs),[1] does a hospital need an order from a physician (or other clinician practitioner acting in accordance with his or her state scope-of-practice requirements) to administer one of the available COVID-19 vaccines to an individual who is requesting COVID-19 immunization?
Answer: CMS, under the waiver authority provided in section 1135 of the Social Security Act (42 U.S.C. 1320b-5), is modifying the requirements at 42 CFR 482.23(c)(3) to allow a hospital to administer any COVID-19 vaccine, authorized under an FDA Emergency Use Authorization without an individual clinician order. This modification to the CoP requirement is equivalent to the individual order exception currently provided at 42 CFR 482.23(c)(3) for influenza and pneumococcal vaccination orders and their administration. Under the section 1135 waiver authority, COVID-19 vaccines will now be included in this regulatory exception for the duration of the Public Health Emergency (PHE). This will allow hospitals to administer COVID-19 vaccines to patients and other individuals requesting immunization in a manner similar to their previous influenza and/or pneumococcal events. Hospitals must adhere to any state law or administrative requirements regarding the administration of vaccinations.

[1] Please note that this discussion of the Medicare hospital CoP order requirements, which apply to all Medicare-participating hospitals and all hospital patients, and which is contained in the FAQ here, clarifies CMS enforcement of those specific hospital CoP requirements only. However, the requirements for payment under Medicare, particularly those related to hospital patient orders, and which apply to hospital services provided to Medicare beneficiaries only, may differ from the CoPs in both their composition and application.

We recognize the pressing need to ensure broad access to available COVID-19 vaccines and the essential role hospitals fill in serving their communities. This includes hospitals hosting, either on campus or offsite, mass immunization events that are easily accessible for those members of the community requesting immunization. These events (similar to annual influenza immunization programs) are typically governed by state law and practice. CMS policy allows participating hospitals (including critical access hospitals and other Medicare-enrolled provider and supplier types) to serve as "mass immunizers" of the COVID-19 vaccines without any additional enrollment (https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots).

CMS recommends that a hospital planning to provide this essential service to its community follow all state laws and administrative requirements, in addition to the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices guidelines for safe vaccine administration (https://www.cdc.gov/vaccines/covid-19/index.html).
New: 2/19/21

F. Hospital Inpatient Prospective Payment Systems (IPPS) Payments

1. **Question**: What are the provisions of section 3710 of the CARES Act?
   Answer: Section 3710 of the CARES Act directs the Secretary to increase the IPPS weighting factor of the assigned diagnosis-related group (DRG) by 20 percent for an individual diagnosed with COVID-19 discharged during the COVID-19 public health emergency period.
   New: 5/27/20

2. **Question**: How will discharges for individuals diagnosed with COVID-19 be identified?
   Answer: A discharge of an individual diagnosed with COVID-19 will be identified by the presence of the following International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes
   - B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020.
   - U07.1 (COVID-19) for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 public health emergency period.

   (For additional information on diagnosis coding related to COVID-19, refer to the FAQs for *Diagnosis Coding under International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)* found above.)
   New: 5/27/20

3. **Question**: How did CMS implement the increased payment under the IPPS for COVID-19 patients under the provisions of section 3710 of the CARES Act?
   Answer: To implement this temporary statutory adjustment, the IPPS Pricer will apply an

adjustment factor to increase the Medicare Severity-Diagnosis Related Group (MS-DRG) relative weight that would otherwise apply by 20 percent when determining IPPS operating payments (including the calculation of payments such as for disproportionate share hospitals (DSHs), indirect medical education (IME), outliers, new technologies, and low-volume hospitals and the hospital specific rates for sole community hospitals (SCHs) and Medicare-dependent hospitals (MDHs)) for discharges of patients with a principal or secondary diagnosis of COVID-19. For additional information regarding which claims are eligible for the 20 percent increase in the MS-DRG weighting factor, please see the Medicare Learning Network (MLN) Matters article "New COVID-19 Policies for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act" available on the CMS website at https://www.cms.gov/files/document/se20015.pdf.
Updated: 1/7/21

4. **Question**: Is the DR condition code required on the claim to receive the increased payment for IPPS discharges of patients diagnosed with COVID-19 provided by section 3710 of the CARES Act?
   Answer: No. The DR condition code is not required since this is a legislative change in IPPS payments.
   New: 5/27/20

5. **Question**: Did CMS create new MS-DRG weights under the IPPS to implement section 3710 of the CARES Act?
   Answer: No, CMS did not create new MS-DRG weights to implement the 20 percent increase in the MS-DRG weight provided by the CARES Act. Rather, in accordance with section 3710 of the Cares Act, for discharges during the emergency period of patients diagnosed with COVID-19, CMS will multiply the current MS-DRG relative weight for the discharge by a factor of 1.20 when calculating a hospital's operating IPPS payment.
   New: 5/27/20

6. **Question**: What are the estimated MS-DRG payments under the IPPS, including the adjustment provided by section 3710 of the CARES Act, for patients diagnosed with COVID-19 and discharged on and after January 27, 2020, and on or before March 31, 2020?
   Answer: The following table provides examples to illustrate the increase in IPPS operating MS-DRG payments provided by the CARES Act for patients diagnosed with COVID-19 (identified by the presence of ICD-10-CM diagnosis code B97.29) for discharges occurring on and after January 27, 2020, and on or before March 31, 2020.

Discharges on and after January 27, 2020, and on or before March 31, 2020	MS-DRG Assignment	FY 2020 Relative Weight[1]	Estimated MS-DRG Payment under the CARES Act[2]
Principal Diagnosis • J12.89 - Other viral pneumonia Secondary Diagnosis • B97.29 - Other coronavirus as the cause of diseases classified elsewhere • J96.01 - Acute respiratory failure with hypoxia (MCC)	MS-DRG 193 Simple Pneumonia and Pleurisy with MCC	1.3335	$9,275.77
Principal Diagnosis • J20.8 - Acute bronchitis due to other specified organisms Secondary Diagnosis • B97.29 - Other coronavirus as the cause of diseases classified elsewhere	MS-DRG 203 Bronchitis and Asthma without CC/MCC	0.6938	$4,826.04
Principal Diagnosis • J22 - Unspecified acute lower respiratory infection Secondary Diagnosis • B97.29 - Other coronavirus as the cause of diseases classified elsewhere	MS-DRG 206 Other Respiratory System Diagnoses without MCC	0.8725	$6,069.07
Principal Diagnosis • J80 - Acute respiratory distress syndrome Secondary Diagnosis • B97.29 - Other coronavirus as the cause of diseases classified elsewhere Procedures • 5A1955Z - Respiratory ventilation, greater than 96 consecutive hours	MS-DRG 207 Respiratory System Diagnosis with Ventilator Support >96 Hours	5.7356	$39,896.58

Principal Diagnosis • O98.513 - Other viral diseases complicating pregnancy, third trimester Secondary Diagnosis • J20.8 - Acute bronchitis due to other specified organisms • B97.29 - Other coronavirus as the cause of diseases classified elsewhere	MS-DRG 833 Other Antepartum Diagnoses without O.R. Procedure without CC/MCC	0.5321	$3,701.26
Principal Diagnosis • A41.89 - Other specified sepsis Secondary Diagnosis • B20 - Human immunodeficiency virus [HIV] disease (CC) • J12.89 - Other viral pneumonia (MCC) • B97.29 - Other coronavirus as the cause of diseases classified elsewhere Procedures • 5A1955Z - Respiratory ventilation, greater than 96 consecutive hours	MS-DRG 974 HIV with Major Related Condition with MCC	2.6739	$18,599.53

[1] See FY 2020 IPPS Final Rule and Correction Notice Table 5 (tab 'FY 2020 Table 5 CN') found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables.

[2] Estimated Operating MS-DRG Payment under the CARES Act based on FY 2020 Standardized amount with a wage index of 1.0 of $5,796.63 (see FY 2020 IPPS Final Rule and Correction Notice Tables 1A-1E (tab 'FY 2020 CN Table 1A-1E') found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables) for hospitals that submitted quality data and are meaningful EHR users. Note this estimated operating IPPS payment does not include any other payment adjustments, such as payments for Disproportionate Share Hospitals (DSHs), Indirect Medical Education (IME), outliers, and the hospital specific rates for Sole Community Hospitals (SCHs) and Medicare-Dependent Hospitals (MDHs).

New: 5/27/20

7. Question: What would the estimated MS-DRG payments under the IPPS, including the adjustment provided by section 3710 of the CARES Act, for patients diagnosed with COVID-19 and discharged on or after April 1, 2020, through the duration of the COVID-19 public health emergency period?

Answer: The following table provides examples to illustrate the increase in IPPS operating MS-DRG payments provided by the CARES Act for patients diagnosed with COVID-19 (identified by the presence of ICD-10-CM diagnosis code U07.1) for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE period.

***Discharges on or after April 1, 2020,* through the duration of the COVID-19 public health emergency period**	**MS-DRG Assignment**	**FY 2020 Relative Weight[1]**	**Estimated MS-DRG Payment under the CARES Act[2]**
Principal Diagnosis • U07.1 - COVID-19 Secondary Diagnosis • J12.89 - Other viral pneumonia (MCC) • J96.01 - Acute respiratory failure with hypoxia (MCC)	MS-DRG 177 Respiratory Infections and Inflammations with MCC	1.8912	$13,155.10
Principal Diagnosis • U07.1 - COVID-19 Secondary Diagnosis • J22 - Unspecified acute lower respiratory infection • N17.9 - Acute kidney failure, unspecified (CC)	MS-DRG 178 Respiratory Infections and Inflammations with CC	1.2433	$8,648.34
Principal Diagnosis • U07.1 - COVID-19 Secondary Diagnosis • J20.8 - Acute bronchitis due to other specified organisms	MS-DRG 179 Respiratory Infections and Inflammations without CC/MCC	0.8661	$6,024. 55

Discharges on or after April 1, 2020, **through the duration of the COVID-19 public health emergency period**	**MS-DRG Assignment**	**FY 2020 Relative Weight[1]**	**Estimated MS-DRG Payment under the CARES Act[2]**
Principal Diagnosis • U07.1 - COVID-19 Secondary Diagnosis • J80 - Acute respiratory distress syndrome (MCC) Procedures • 5A1955Z - Respiratory ventilation, greater than 96 consecutive hours	MS-DRG 207 Respiratory System Diagnosis with Ventilator Support >96 Hours	5.7356	$39,896.58
Principal Diagnosis • O98.513 - Other viral diseases complicating pregnancy, third trimester Secondary Diagnosis • U07.1 - COVID-19 (MCC) • J20.8 - Acute bronchitis due to other specified organisms	MS-DRG 831 Other Antepartum Diagnoses without O.R. Procedure with MCC	1.0785	$7,502.00
Principal Diagnosis • A41.89 Secondary Diagnosis • B20 - Human immunodeficiency virus [HIV] disease (CC) • U07.1 - COVID-19 (MCC) • J12.89 - Other viral pneumonia (MCC) Procedures • 5A1955Z - Respiratory ventilation, greater than 96 consecutive hours	MS-DRG 974 HIV with Major Related Condition with MCC	2.6739	$18,599.53

Discharges on or after April 1, 2020, **through the duration of the COVID-19 public health emergency period**	**MS-DRG Assignment**	**FY 2020 Relative Weight[1]**	**Estimated MS-DRG Payment under the CARES Act[2]**

[1] See FY 2020 IPPS Final Rule and Correction Notice Table 5 (tab 'FY 2020 Table 5 CN') found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables.https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables.

[2] Estimated Operating MS-DRG Payment under the CARES Act based on FY 2020 Standardized amount with a wage index of 1.0 of $5,796.63 (see FY 2020 IPPS Final Rule and Correction Notice Tables 1A-1E (tab 'FY 2020 CN Table 1A-1E') found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables) for hospitals that submitted quality data and are meaningful EHR users. Note this estimated operating IPPS payment does not include any other payment adjustments, such as payments for Disproportionate Share Hospitals (DSHs), Indirect Medical Education (IME), outliers, and the hospital specific rates for Sole Community Hospitals (SCHs) and Medicare-Dependent Hospitals (MDHs).
New: 5/27/20

8. **Question**: Does the increased IPPS payment under section 3710 of the CARES Act apply to a hospital's capital IPPS payments?
   Answer: No. Section 3710 of the CARES Act amended Section 1886(d)(4)(C) of the Social Security Act which generally governs IPPS operating payments. Therefore, in calculating a hospital's capital IPPS payment the MS-DRG weights are not adjusted for a patient diagnosed with COVID-19 and discharged during the emergency period.
   New: 5/27/20

9. **Question**: How does the increased payment under section 3710 of the CARES Act affect a hospital's IPPS high cost outlier payment?
   Answer: The FY 2020 fixed-loss amount of $26,552 was not adjusted by the CARES Act. High cost outlier payments for IPPS discharges during the emergency period with a COVID-19 diagnosis code are determined after applying the increased payment under section 3710 of the CARES Act.
   New: 5/27/20

10. **Question**: Does the increased payment under section 3710 of the CARES Act apply to hospital-specific rate payment for sole community hospitals (SCHs) and Medicare-dependent hospitals (MDHs)?
    Answer: Yes, for IPPS discharges during the emergency period that have a principal or secondary COVID-19 diagnosis code, CMS will multiply the current MS-DRG relative weight for the discharge by a factor of 1.20 when calculating the hospital-specific rate payment for SCHs and MDHs.
    New: 5/27/20

11. **Question**: Will cases subject to the IPPS transfer policies receive the 20 percent increase for patients diagnosed with COVID-19 under the CARES Act?
    Answer: Yes. For IPPS discharges of patients diagnosed with COVID-19 that are subject to the transfer policy, the MS-DRG relative weight is increased by 20 percent when calculating the hospital's operating IPPS payment.
    New: 5/27/20

12. **Question**: How will claims processed before implementation of the provisions of section 3710 of the CARES Act be handled? Will the claims need to be resubmitted to receive the increased IPPS payment for discharges of patients diagnosed with COVID-19?
    Answer: MACs will automatically initiate the reprocessing of affected claims by June 1, 2020. Affected claims are identified by the presence of ICD-10-CM diagnosis code B97.29 (for discharges occurring on and after January 27, 2020, and on or before March 31, 2020) and diagnosis code U07.1 (for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE period).
    New: 5/27/20

13. **Question:** What is the new COVID-19 treatments add-on payment (NCTAP) under the Inpatient Prospective Payment System (IPPS)?
    Answer: In order to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments during the COVID-19 PHE, the Medicare program will provide an enhanced payment for eligible inpatient cases that involve use of certain new products authorized or approved to treat COVID-19. In Medicare, hospitals are generally reimbursed a fixed payment amount for the services they provide during an inpatient stay, even if their costs exceed that amount. Under current rules, hospitals may qualify for an additional "outlier payment," but only when their costs for a particular patient exceed a certain threshold. The NCTAP allows hospitals to qualify for additional payments when they treat patients with certain new products approved or authorized to treat COVID-19. The enhanced payment will be equal to the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the cost of a COVID-19 stay beyond the operating Medicare payment (including the 20 percent add-on payment under section 3710 of the CARES Act) for eligible cases.

CMS anticipates that monoclonal antibody products to treat COVID-19 will initially be given to health care providers at no charge. Medicare will not pay for the monoclonal antibody products to treat COVID-19 that health care providers receive for free but will provide payment for the infusion (that is, administration) of the product during the COVID-19 PHE, when furnished consistent with the EUA. When health care providers begin to purchase these monoclonal antibody products, CMS anticipates setting the Medicare payment rate in the same way it anticipates setting the payment rates for other COVID-19 vaccines when administered in the hospital inpatient setting, which is based on reasonable cost. Note that Medicare pays for these monoclonal antibody products under the COVID-19 vaccine benefit and, therefore, these products are not eligible for the NCTAP under the IPPS.
New: 12/3/20

14. **Question:** What happens to the new COVID-19 treatments add-on payment (NCTAP) if an approved product loses its EUA status?
Answer: The FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program. The program uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether they are helpful or harmful. Additional information regarding this program is available on the FDA website at https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap.

One aspect of the program is the issuance by the FDA of Emergency Use Authorizations (EUAs) during the COVID-19 PHE. More information regarding EUAs for drug and biological products during the COVID-19 PHE is available on the FDA website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

For a case to be eligible for NCTAP, it must meet certain criteria. One criterion is that the case must include the use of a drug or biological product authorized to treat COVID-19 as indicated in section "I. Criteria for Issuance of Authorization" of the current letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19. Because the purpose of the NCTAP is to mitigate potential financial disincentives for hospitals to provide new COVID-19 treatments, this criterion expeditiously provides assurance in the context of the urgency of the PHE that a treatment is new and is used to treat COVID-19 during the PHE. Therefore, a product without a current EUA or FDA approval for treating COVID-19 is not eligible for NCTAP.
New: 12/3/20

G. Hospital Outpatient – Locations off of Hospital Campus

1. **Question:** When hospital clinical staff furnish a service using telecommunication technology to the patient who is a registered outpatient of the hospital and the hospital makes the patient's home provider-based to the hospital as a temporary expansion site, should the hospital bill using the telehealth modifier (modifier 95)?
   Answer: No. In this situation the hospital is furnishing an outpatient hospital service, not a telehealth service, to a patient in a temporarily relocated department of the hospital as discussed at 85 FR 27560. Accordingly, the hospital would bill as it ordinarily would bill and would include the DR condition code or CR condition code (as applicable) on the claim. If the situation involves a relocation of an on-campus or excepted off-campus provider-based department to an off-campus hospital location, the hospital would bill using the PO modifier (service provided at an excepted off-campus provider-based department) only if the hospital requests an extraordinary circumstances relocation request within 120 days of the date the temporary expansion site is made provider-based to the hospital; otherwise, the hospital would append the PN modifier (service provided at a non-excepted off-campus provider-based department) to claims from the relocated hospital location.
   New: 6/16/20

2. **Question:** What is CMS' current policy regarding relocating excepted and non-excepted provider-based departments? What is different under the new Interim Final Rule with comment?
   Answer: Under Section 603 of the Bipartisan Budget Act of 2015, new off-campus provider-based departments (PBDs) that start billing Medicare after November 2, 2015, are considered "non-excepted" and are paid for items and services under the "applicable payment system" rather than the Outpatient Prospective Payment System (OPPS). CMS determined that the Medicare Physician Fee Schedule (PFS) was the applicable payment system for applicable services billed by non-excepted departments. Effective since 2018, the PFS Relativity Adjuster that applies to these services is 40 percent of the OPPS rate.

   In 42 CFR 419.48(a)(2), CMS established a policy that excepted off-campus PBDs that have not impermissibly relocated can remain excepted. Generally speaking, this means that excepted PBDs that relocate will typically lose their excepted status and be paid under the PFS instead. However, in the CY 2017 OPPS/ASC final rule (81 FR 79704–06), we finalized a policy to allow excepted off-campus PBDs to relocate, temporarily or permanently, without loss of excepted status, for extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues.

   Under the CMS IFC published in the Federal Register on May 8th, CMS is temporarily expanding the extraordinary circumstances relocation exception policy during the PHE to include *both* on-campus and excepted off-campus PBDs that relocate (or partially relocate)

to new off-campus locations, including to any temporary expansion locations (such as other sites or the patient's home, as applicable), due to the PHE. This policy applies to relocations occurring on or after March 1, 2020 (85 FR 27560) and will last until the end of the PHE. Further, CMS is streamlining the process for relocating PBDs to seek an exception, and will allow PBDs to immediately begin furnishing and billing for services at the new location while the regional office is reviewing the exception request.
New: 6/19/20

3. **Question:** How can a hospital apply for the temporary extraordinary circumstances relocation exception for relocated on-campus and excepted off-campus provider-based departments that is in effect during the PHE?
Answer: Under the second IFC, CMS established a new streamlined process for hospitals seeking a temporary exception for an on-campus or excepted off-campus PBD that relocates off-campus due to the PHE. We note that the relocation must not be inconsistent with the state's emergency preparedness or pandemic plan. Under the new streamlined process:
New: 6/19/20

   A. Hospitals can begin furnishing services immediately in the relocated off-campus PBD and bill for them using the "PO" modifier. This modifier indicates the service was provided at an excepted off-campus PBD and is paid the OPPS payment rate.
   B. Within 120 days of beginning to furnish and bill for services at the relocated off-campus PBD, the hospital must email the applicable CMS Regional Office with seven pieces of information:
      a) The hospital's CCN;
      b) The date the hospital began to furnish services at the new location;
      c) The address of the original on-campus PBD or excepted off-campus PBD (or partially relocated PBD, as applicable);
      d) The new address(es) of the relocated PBD(s);
      e) A brief description of the justification for the relocation, the role of the relocation in the hospital's operations in addressing COVID-19, and why the new PBD location is appropriate for furnishing covered outpatient items and services;
      f) An attestation that the relocation(s) is/are not inconsistent with the state's emergency preparedness or pandemic plan; and
      g) A point of contact (name, title, telephone, email) at the hospital for the request.

   C. Note that, for hospitals that are relocating (or partially relocating) a single PBD to more than one new location, the hospital may supply a single CCN, address of the original PBD, justification and attestation, as long as the hospital indicates that they apply to all of the new PBD relocation requests. Hospitals should encrypt the relocation request information prior to sending it to their CMS regional office by email.

D. If Medicare-certified hospitals will be rendering services in relocated excepted PBDs, but intend to bill Medicare for the services under the main hospital, no additional provider enrollment actions are required (for example, hospitals do not need to submit an updated CMS-855A enrollment form) for the off-campus relocated PBD during the COVID-19 PHE.

The OMB Control Number for the Paperwork Reduction Act Notice for the temporary extraordinary circumstances relocation request process is 0938-1376.
New: 6/19/20

4. **Question:** Under the temporary extraordinary circumstances relocation exception policy, hospitals are required to provide certain information to their applicable CMS Regional Office within 120 days of beginning to furnish and bill for care at the new location. What email address should hospitals use for each region?
   Answer: We have listed the appropriate email addresses for the Regional Offices here. Of note, some of the regions are consolidated and thus have one email address representing two regions:

   - Boston and New York: OPOLE_IFM_BOSNY_AR@cms.hhs.gov
   - Philadelphia: OPOLE_IFM_PHI_AR@cms.hhs.gov
   - Atlanta: OPOLE_IFM_ATL_AR@cms.hhs.gov
   - Chicago and Kansas City: OPOLE_IFM_CHIKCGP_AR@cms.hhs.gov
   - Dallas and Denver: OPOLE_IFM_DALDENGP_AR@cms.hhs.gov
   - San Francisco and Seattle - OPOLE_IFM_SFSEA_AR@cms.hhs.gov

   New: 6/19/20

5. **Question:** Must a hospital that wishes to relocate a provider-based department apply for a Temporary Extraordinary Circumstances Relocation Request? If not, if an on-campus or excepted off-campus provider-based department relocates and does not seek a Temporary Extraordinary Circumstances Relocation Request, what modifier should the hospital include on the claim line for a service provided at the relocated provider-based department?
   Answer: A hospital does not need to submit a temporary extraordinary circumstances relocation request if it intends to bill the services provided as non-excepted services paid at the PFS-equivalent rate. If an on-campus or excepted off-campus provider-based department relocates (including to a home) and does not seek a temporary extraordinary circumstances relocation request, the hospital should bill services with the “PN” modifier so that the services are paid the non-excepted PFS-equivalent rate.
   New: 6/19/20

6. **Question:** If an on-campus or excepted off-campus provider-based department applies for a Temporary Extraordinary Circumstances Relocation Request, what modifier should the hospital include on the claim line for a service provided at the relocated department?
Answer: A hospital with an on-campus provider-based department (PBD) that relocates off-campus (including to a home) for the PHE and applies for a Temporary Extraordinary Circumstances Relocation Request would bill for services provided by that department with the "PO" modifier, which indicates a service was provided at an excepted off-campus PBD. It would be paid the OPPS payment rate (including the reduced rate for visits at excepted off-campus departments).

- A hospital with an excepted off-campus PBD that relocates to a new off-campus location (including to a home) for the PHE and applies for a Temporary Extraordinary Circumstances Relocation Request would continue to bill for services provided by that department with a "PO" modifier and be paid under the OPPS (including the reduced rate for clinic visits at excepted off-campus departments).

- A non-excepted off-campus PBD is not eligible for a Temporary Extraordinary Circumstances Relocation Request. The hospital would continue to bill services provided by that department with the "PN" modifier.

Note: If a hospital is notified that the CMS Regional Office has denied its Temporary Extraordinary Circumstances Relocation Request for a relocated department, the hospital should bill for services provided by that department with the "PN" modifier.
New: 6/19/20

7. **Question:** Under the new process to seek an extraordinary circumstances relocation exception that is in place during the COVID-19 PHE, do hospitals need to submit a relocation request for *every* location to which its PBD relocates, including in circumstances where the excepted PBD relocates to several different patients' homes?
Answer: Hospitals have 120 days from the date on which they begin furnishing services at a relocated PBD to submit a temporary extraordinary circumstances relocation exception request (85 FR 27561). As part of a relocation exception request, hospitals should notify their CMS Regional Office by email of the addresses of the locations to which its PBD relocates. Hospitals are not required to submit a separate email for every relocation site. Hospitals can send a request that includes all of the addresses to which the PBD relocated over a period of weeks or months, rather than a single request for each location. The hospital should also notify the Regional Office of the addresses of any patients' homes to which the PBD relocates if the hospital intends to be paid under the OPPS for these services. If a hospital chooses <u>not</u> to submit a patient's home address for an extraordinary circumstances relocation request, the hospital can simply bill for services provided at such relocation site with the "PN" modifier and receive payment at the PFS-equivalent rate for

those services.
New: 6/19/20

8. **Question:** A hospital relocated an excepted PBD to a patient's home during the PHE. If the hospital wanted to be paid the OPPS rate, must the hospital send all new PBD location addresses (including a patient's address) to the CMS Regional Office as part of the extraordinary circumstances relocation request?
   Answer: Yes, a hospital would need to send each new PBD location address to CMS to seek an extraordinary circumstances relocation exception and be paid the OPPS rate. Hospitals should not include any unnecessary personally identifiable information, such as beneficiary name or diagnosis, on the relocation request. Hospitals should encrypt the relocation request information prior to sending it to their CMS regional office by email.
   New: 6/19/20

9. **Question:** A hospital is relocating a single excepted PBD to several new locations and is seeking an extraordinary circumstances exception. Other than the addresses and the dates that care was first provided at the new PBD locations, all of the other pieces of information requested by CMS are the same for each new PBD location. In this situation, can the hospital submit a list of the relocated PBD addresses (for example, in an encrypted Microsoft Excel file), as well as the date that care was first delivered in each new location, while the body of the relocation request email indicates that certain pieces of information (e.g., the hospital's CCN, the justification, and the attestation) apply to all of the new PBD relocations contained in the Microsoft Excel file?
   Answer: Yes. In circumstances where the hospital is relocating the same excepted PBD to multiple new PBD locations, the hospital may identify that a single CCN, single address of the original PBD location, single justification, single attestation, and single point of contact apply to all of the new PBD locations without having to copy those pieces of information for each new location.
   New: 6/19/20

10. **Question:** A hospital has an excepted PBD that relocated to a patient's home during the PHE and submitted an extraordinary circumstances relocation request with its CMS Regional Office. After this, the excepted PBD needed to relocate to the same patient's home at least one more time during the PHE. Does the hospital need to submit an extraordinary circumstances relocation request every time the excepted PBD relocates to the same patient's home address?
    Answer: No. A PBD only needs to submit a relocation request for a particular address once, regardless of how often the PBD provides services at that location.
    New: 6/19/20

11. **Question:** A hospital has two different excepted PBDs that both relocate to the same patient's home during the PHE. Does the hospital need to submit an extraordinary circumstances relocation request for each provider-based department?
Answer: Yes. Each PBD must submit a request for each location that it will be providing services. The hospital may submit the request for each PBD to relocate to the patient's home address in the same email (or separate emails) to the RO.
New: 6/19/20

12. **Question:** A hospital has to relocate its current on-campus or excepted off-campus provider-based department to multiple new off-campus locations during the COVID-19 public health emergency. Is this allowed during the COVID-19 public health emergency (PHE) and does each location retain excepted status?
Answer: Yes. To provide additional flexibility, for purposes of addressing the PHE, hospitals may divide their on-campus or excepted off-campus PBD into multiple locations. That is, if a single excepted PBD location relocates to multiple off-campus PBD locations to provide needed care during the COVID-19 PHE, it will be permissible for all of the off-campus PBDs locations to which the excepted PBD relocated to continue to bill under the OPPS under the revised extraordinary circumstances policy that is in place during the COVID-19 PHE. We note that hospitals relocating these departments should follow the process discussed in the Q&A above to notify their CMS Regional Office within 120 days of beginning to furnish and bill for services in the relocated PBDs. In addition, under the circumstances where the hospital is relocating an on-campus or excepted off-campus PBD to multiple locations, the hospital should notify the CMS Regional Offices of the addresses for all new PBD locations.

    Please note that in most cases we do not anticipate that excepted PBDs would need to relocate into many different new locations. Rather, we anticipate in most cases that relocations would be to a limited number of locations as needed to respond to the PHE in a manner not inconsistent with the state's emergency preparedness and pandemic plan, with the exception being multiple relocations to accommodate care in patient's homes. We also expect that hospitals exercising this flexibility should be able to support that the excepted PBD is still the same PBD, just relocated into more than one location. For example, if the excepted PBD was an oncology clinic, we would expect that the relocated PBD(s) during the PHE would still be providing oncologic services, including in the patient's home to the extent such location is made provider-based to the hospital.
    New: 6/19/20

13. **Question:** A hospital relocated its existing on-campus or excepted off-campus provider-based department during the COVID-19 PHE. Instead of moving back, it wants to *permanently* relocate the PBD to the new off-campus location. Will the relocated PBD still be considered excepted after the public health emergency ends?
Answer: No. The temporary extraordinary circumstances exception policy is time-limited to

the COVID-19 PHE to enable short-term hospital relocation of on-campus and excepted off-campus provider-based departments to improve access to care for patients. The temporary extraordinary circumstances relocation policy ends when the COVID-19 PHE ends. For hospitals that choose to permanently relocate these PBDs off-campus, they would be considered "new" off-campus PBDs and therefore would be required to bill using the "PN" modifier and would be paid the PFS-equivalent rate following the end of the COVID-19 PHE.

Following the COVID-19 PHE, hospitals may seek an extraordinary circumstances relocation exception for excepted off-campus locations that have permanently relocated, but these hospitals would need to follow the standard extraordinary circumstances application process we adopted in CY 2017 and file an updated CMS-855A enrollment form to reflect the new address of the PBD. We note that hospitals should not rely on having relocated the PBD during the COVID-19 PHE as the reason the PBD should be permanently excepted following the end of the COVID-19 PHE. In other words, the fact that the PBD relocated in response to the COVID-19 pandemic will not, by itself, be considered an "extraordinary circumstance" for purposes of a permanent relocation exception. The CMS Regional Offices will maintain discretion whether to approve or deny these requests that apply after the COVID-19 PHE, depending on whether the relocation request meets the extraordinary circumstances exception.
New: 6/19/20

14. **Question:** A hospital wants to *partially relocate* an existing on-campus or excepted off-campus provider-based department during the COVID-19 public health emergency (PHE) by maintaining the existing PBD but starting one or more new off-campus PBD locations. Does the new temporary extraordinary circumstances policy apply to these locations during the COVID-19 PHE?
    Answer: Yes. For purposes of the COVID-19 PHE, hospitals may relocate part of their on-campus or excepted off-campus PBD to a new off-campus location while maintaining the original PBD location. Said differently, if a single PBD relocates part of an excepted PBD to one or more off-campus PBD locations, it would be permissible for the original excepted PBD location, as well as the relocated off-campus PBD location(s) of that excepted PBD, to continue to bill under the OPPS under the revised extraordinary circumstances policy that is in place during the COVID-19 PHE so long as the extraordinary circumstances policy in effect during the COVID-19 PHE is followed.
    New: 6/19/20

15. **Question:** A hospital wants to relocate one of its on-campus or excepted off-campus provider-based departments to a patient's home to be able to furnish care in the home during the COVID-19 public health emergency. Can the patient's home be considered a relocated provider-based department during the public health emergency? Does that relocation fall under the new temporary extraordinary circumstances relocation policy?

Answer: Yes, the patient's home can be considered a relocated hospital PBD during the COVID-19 PHE. Under the Hospital Without Walls initiative, CMS waived the requirements for being a provider-based department of the hospital in 42 CFR 413.65, as well as certain (but not all) Medicare conditions of participation in § 482.41 and 485.623, to facilitate the availability of temporary expansion locations. These waivers allow hospitals to create temporary expansion locations to broaden access, and expansion sites can include tents, convention centers, and patients' homes, as long as the hospital can continue to meet the conditions of participation that remain in effect during the COVID-19 PHE.

Importantly, these waivers do not determine whether a new temporary expansion location that is a provider-based department is excepted or non-excepted for purposes of Section 603 of the Bipartisan Budget Act of 2015 ("Section 603"). As a result, if the hospital considers the patient's home a *new* PBD, it would be non-excepted for purposes of Section 603. However, if the hospital considers the patient's home a relocated (or partially relocated) PBD, and the Regional Office approves the relocation under the temporary extraordinary circumstances exception policy in effect during the COVID-19 PHE (and discussed in more detail in the other FAQs), the PBD would be considered excepted and the hospital could add the "PO" modifier to claims for services furnished at that location and would be paid the full OPPS rate.
New: 6/19/20

16. **Question:** A hospital has relocated an on-campus or excepted off campus provider-based department (PBD) during the COVID-19 PHE under the temporary extraordinary circumstances exception policy. What billing rules do these locations need to follow? Do the "CR" or "DR" modifiers need to be applied to OPPS claims for services furnished at the new location(s)?
Answer: Hospitals should add the "CR" and "DR" modifiers to all claims as applicable where a CMS waiver was necessary, including claims for services furnished at relocated PBDs that are acting as temporary expansions locations during the COVID-19 PHE.

We also note that if Medicare-certified hospitals will be rendering services in relocated excepted PBDs, but intend to bill Medicare for the services under the main hospital, no additional provider enrollment actions are required (for example, hospitals do not need to submit an updated CMS-855A enrollment form) for the off-campus relocated PBDs during the COVID-19 PHE. Following the COVID-19 PHE, hospitals may seek to make a relocated PBD permanent. If the hospital wishes to retain excepted status for its PBD that is permanently relocating, the hospital could seek an extraordinary circumstances relocation exception for excepted off-campus locations that have permanently relocated. These hospitals would need to follow the standard extraordinary circumstances application process we adopted in CY 2017 and file an updated CMS-855A enrollment form to reflect the new address of the PBD.

New: 6/19/20

17. **Question:** The state government, U.S. Army Corps of Engineers, or other governmental entity established a new care location in our area by repurposing and retrofitting a convention center, gymnasium, tent or other site for patient care. *See* 42 C.F.R. 411.8(b)(4). Following its development, our hospital has been brought in to operate and staff this site with our clinicians. Can we bill Medicare for the facility and professional services our organization provides there? If so are there reporting or billing rules that determine how this is done?
    Answer: Under CMS' Hospital Without Walls initiative, Medicare-enrolled hospitals that assume the majority operations of temporary expansion locations—including gymnasiums, tents, convention centers, and others—that were built or retrofitted by a public entity can bill Medicare for covered inpatient and outpatient hospital services provided to Medicare beneficiaries at those temporary expansion locations. The hospital that operates the temporary expansion location(s) would need to continue to meet the conditions of participation that remain in effect during the COVID-19 PHE. Hospitals may relocate PBDs to these locations. Hospitals would need to follow existing rules to bill under the applicable Medicare payment system depending on whether they provided outpatient care or inpatient care. Hospitals should add the "DR" condition code to inpatient and outpatient claims for patients treated in temporary expansion sites during the Public Health Emergency. Similarly, Medicare enrolled practitioners can bill Medicare for furnishing covered professional services to Medicare beneficiaries in these temporary expansion sites. Practitioners should use the applicable place of service code depending on whether the temporary expansion site is being used to furnish outpatient or inpatient care. Also, practitioners should add the modifier "CR" to professional claims for patients treated in temporary expansion sites during the Public Health Emergency.
    New: 6/19/20

H. Hospital Outpatient Therapeutic Services Furnished In Temporary Expansion Locations

1. **Question:** Can hospital outpatient therapy, education, and training services that can be furnished other than in person be furnished in a temporary expansion location (which may be the patient's home) that is a PBD of the hospital during the PHE?
    Answer: Yes, as long as facility staff can effectively furnish these services using telecommunication technology, the hospital service does not require the clinical staff and patient to be in the same location to furnish the service, the patient is registered as an outpatient of the hospital, and the service is furnished under the physician's overall direction and control. CMS has already stated that section 1135 blanket waivers in effect during the COVID-19 PHE allow the hospital to consider the patient's home, and any other temporary expansion location operated by the hospital during the COVID-19 PHE, to be a PBD of the hospital, so long as the hospital can ensure the locations meet all of the conditions of

participation, to the extent not waived.

To facilitate public understanding of the types of services we believe can be furnished by the hospital to a patient in the hospital (including the patient's home if it is provider-based) using telecommunications technology, we have provided on our website a list of the outpatient therapy, counseling, and educational services that hospital staff can furnish incident to a physician's or qualified non-physician practitioner's service during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location, that functions as a provider-based department of the hospital when the beneficiary is registered as an outpatient of the hospital, using telecommunications technology. We note that this list may not include every service that falls into this category. We intend to update the list periodically, to the extent that would be helpful for public awareness. The list is available at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

We note that hospitals may bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare in general, including any relevant modifications in effect during the COVID-19 PHE.
New: 6/19/20

2. **Question:** Can hospitals bill for services that are furnished by clinical staff under a physician's or qualified non-physician practitioner's order that do not require professional work by the physician or qualified non-physician practitioner, when furnished by the hospital in the patient's home that is provider-based to the hospital and are not separately billable under the PFS?
   Answer: Yes, the flexibilities that exist during the COVID-19 PHE enable hospitals to furnish these clinical staff services in the patient's home as a provider-based outpatient department and to bill and be paid for these services as Hospital Outpatient Department (HOPD) services when the patient is registered as a hospital outpatient. The service must be furnished under the physician's overall direction and control. Hospitals should bill for these services as they ordinarily bill for services along with any specific billing requirements for relocating PBDs specific to billing during a COVID-19 PHE. That is, hospitals should bill as if the services were furnished in the hospital, including appending the PO modifier for excepted items and services and the PN modifier for non-excepted services and the DR condition code. The DR condition code is used by institutional providers only, at the claim level, when all of the services/items billed on the claim are related to a COVID-19 waiver. The CR modifier is used by both institutional and non-institutional providers to identify Part B line item services/items that are related to a COVID-19 waiver.

   During the time period that the patient is receiving services from the hospital clinical staff as a registered outpatient, the patient's place of residence cannot be considered a home for

purposes of home health agency (HHA) services. The hospital should be aware if the patient is under a home health plan of care and must not furnish services to the patient that could be furnished by the HHA while the plan of care is active. That is, to the extent that there is some overlap between the types of services a HHA and a HOPD can provide, and the patient has a current home health plan of care, the hospital should only furnish services that cannot be furnished by the HHA.
New: 6/19/20

3. **Question:** When a physician or practitioner who ordinarily practices in the HOPD furnishes a telehealth service to a patient who is located at home, can the hospital bill an originating site fee?
   Answer: When a registered outpatient of the hospital is receiving a telehealth service, the hospital may bill the originating site facility fee to support such telehealth services furnished by a physician or practitioner who ordinarily practices there and bills for the telehealth service that is or would otherwise be furnished in the hospital outpatient department. This includes patients who are at home, when the home is made provider-based to the hospital (which means that all applicable conditions of participation, to the extent not waived, are met).
   New: 6/19/20

I. Partial Hospitalization Program (PHP) Services

1. **Question:** Will the flexibilities that CMS is announcing in this rule allow hospitals and CMHCs to provide PHP services in the home while the patient is registered as an outpatient?
   Answer: Effective as of March 1, 2020, and for the duration of the COVID-19 PHE, consistent with the goals of infection control and maintaining access, hospitals and CMHCs will be permitted to provide certain PHP services remotely using telecommunication technology in a temporary expansion location of the hospital or CMHC that meets all applicable conditions of participation to the extent not waived, and which may include the patient's home to the extent it is made provider-based to the hospital or an extension of the CMHC. The following types of services—to the extent they were already billable as PHP services in accordance with existing coding requirements prior to the COVID-19 PHE—can now be furnished to beneficiaries by facility staff using telecommunications technology during the COVID-19 PHE: (1) individual psychotherapy; (2) patient education; and (3) group psychotherapy. The services must be within a practitioner's scope of practice and in accordance with coding and documentation requirements. Because of the intensive nature of PHP, we expect PHP services to be furnished using telecommunications technology involving both audio and video. However, we recognize that in some cases beneficiaries might not have access to video communication technology. In order to maintain beneficiary access to PHP services, only in the case that both audio-video technology is not possible can the service be furnished exclusively with audio.

New: 6/19/20

2. **Question:** Is CMS waiving or modifying any other requirements for the partial hospitalization program such as the plan of treatment or recertification requirements?
   Answer: No. All other PHP requirements are unchanged and still in effect. Patients receiving partial hospitalization services must be under an individualized plan of treatment as previously established in regulations. Nothing about furnishing services remotely changes the requirement that all services furnished under the PHP require an order by a physician, must be supervised by a physician, must be certified by a physician, and must be furnished by a clinical staff member working within his or her scope of practice. .
   New: 6/19/20

3. **Question:** How should partial hospitalization services that are furnished remotely during the Public Health Emergency be billed?
   Answer: Effective as of March 1, 2020, and for the duration of the PHE for the COVID-19 pandemic, consistent with the goals of infection control and maintaining access, during the Public Health Emergency, partial hospitalization services that are furnished remotely to patients should be billed as if they were furnished in the hospital or Community Mental Health Center (CMHC) with the "DR" condition code.
   New: 6/19/20

J. Ambulance Services

1. **Question:** Can ground ambulance providers and suppliers transport beneficiaries with COVID-19 symptoms, or those who are confirmed to have COVID-19, to destination sites that are not a hospital, critical access hospital (CAH) or skilled nursing facility (SNF)?
   Answer: To provide ground ambulance providers and suppliers the flexibility to furnish medically necessary emergency and non-emergency ambulance transports for beneficiaries during the PHE for the COVID-19 pandemic, we are temporarily expanding the list of allowable destinations for ground ambulance transports. During the COVID-19 PHE, a covered destination for a ground ambulance transport may include any destination that is equipped to treat the condition of the patient in a manner consistent with state and local Emergency Medical Services (EMS) protocols where the services will be furnished. These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, CAH or SNF; community mental health centers; federally qualified health centers; rural health clinics; physician's offices; urgent care facilities; ambulatory surgical centers; any location furnishing dialysis services outside of the ESRD facility when an ESRD facility is not available; and the beneficiary's home. There must be a medically necessary ground ambulance transport of a patient in order for the ambulance service to be covered.
   New: 4/9/20

2. **Question:** How are Advanced Life Support (ALS) assessment, intervention, and ambulance transport defined?
   Answer: Definitions for Ambulance Services are in 42 CFR §414.605. ALS assessment, intervention, and ambulance transport are defined as follows:
   - Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service. ALS intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel. Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.
   - Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures: (1) Manual defibrillation/cardioversion, (2) Endotracheal intubation, (3) Central venous line, (4) Cardiac pacing, (5) Chest decompression, (6) Surgical airway, and (7) Intraosseous line.
     New: 4/9/20

3. **Question:** How is an ALS assessment determined?
   Answer: Medicare ambulance coverage policy provides that an ALS assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service. In the case of an appropriately dispatched ALS emergency service if the ALS crew completes an ALS assessment, the services provided by the ambulance transportation service provider or supplier is covered at the ALS emergency level, regardless of whether the patient required ALS intervention services during the transport, provided that ambulance transportation itself was medically reasonable and necessary and all other coverage requirements are met (see Medicare Benefit Policy Manual, Chapter 10, Section 30.1.1.).
   New: 4/9/20

4. **Question:** Will all transports of COVID-19 patients or patients suspected to have COVID-19 be designated as Advanced Life Support (ALS) transports?

Answer: No. Payment for an ambulance transport is based on the level of service provided.
New: 4/9/20

5. **Question:** Will CMS allow ground ambulance providers and suppliers to treat patients in place during the COVID-19 pandemic?
Answer: Section 9832 of the American Rescue Plan Act of 2021 provides the Secretary with authority to implement a waiver applicable to ground ambulance services during the COVID-19 PHE. Effective March 1, 2020 through the end of the COVID-19 public health emergency, CMS is waiving the requirement under sections 1861(s)(7) and 1834(l) of the Social Security Act that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under 42 CFR § 410.40(f) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the COVID-19 PHE.

   These ground ambulance services may be paid at the base rate that would have been paid under the Ambulance Fee Schedule had the beneficiary been transported, that is, based on the level of services that was furnished, excluding any mileage payment. Pursuant to CMS' implementation of this waiver authority, however, CMS will not permit payment of claims that request payment at the ALS2 level of service. ALS2 is the transportation by ground ambulance vehicle and the provision of medically necessary supplies and services including (1) at least three separate administrations of one or more medications by intravenous (IV) push/bolus or by continuous infusion (excluding crystalloid fluids) or (2) ground ambulance transport, medically necessary supplies and services, and the provision of at least one of the ALS2 procedures: manual defibrillation/cardioversion; endotracheal intubation; central venous line; cardiac pacing; chest decompression; surgical airway; or intraosseous line. CMS believes that services furnished at this level of intensity would also require transport to a Medicare covered destination (likely a hospital) and would not be consistent with services able to be rendered as treatment in place.

   Under the waiver, if the ambulance services are furnished by a CAH or by an entity that is owned or operated by a CAH, payment would continue to be made at 101 percent of reasonable costs, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. If there is no provider or supplier of ambulance services within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services

to the CAH.

CMS will pay for treatment in place under the waiver in cases where the individual that would have been transported would have met the Medicare criteria for a medically necessary ground ambulance transport to the nearest appropriate facility that could have treated the patient's condition, but such transport did not occur as a result of community-wide EMS protocols due to the COVID-19 PHE. The beneficiary's condition must have required both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Payment for these treatment in place cases will be made at either the BLS emergency rate or ALS-1 emergency rate including applicable adjustments to the base rate.
Revised: 5/5/21

6. **Question:** Should HCPCS code A0998 (ambulance response and no transport) or A0433 (ambulance service, advanced life support, level 2 (ALS2)) be reported for treatment in place?
   Answer: No. HCPCS code A0998 should not be assigned for treatment in place. ALS2 requires a level of care that is not consistent with any known community-wide EMS protocols for treatment in place. ALS2 is the transportation by ground ambulance vehicle and the provision of medically necessary supplies and services including (1) at least three separate administrations of one or more medications by intravenous (IV) push/bolus or by continuous infusion (excluding crystalloid fluids) or (2) ground ambulance transport, medically necessary supplies and services, and the provision of at least one of the ALS2 procedures: manual defibrillation/cardioversion; endotracheal intubation; central venous line; cardiac pacing; chest decompression; surgical airway; or intraosseous line. CMS believes that services furnished at this level of intensity would also require transport to a Medicare covered destination (likely a hospital) and would not be consistent with services able to be rendered as treatment in place.
   Revised: 5/5/21

7. **Question:** Will CMS allow all responses, including Basic Life Support (BLS), related to COVID-19 to be billed at the ALS rate, regardless if ALS interventions were performed?
   Answer: We recognize that COVID-19 transports require following infectious disease protocols, such as decontamination procedures, personal protective equipment (PPE), and the required engagement of paramedics which may increase the cost of transports involving suspected or diagnosed COVID-19 patients. However, ground ambulance transports must be billed according to the level of service furnished. Only transports that meet the requirements for billing at the ALS level of service can be billed at the ALS rate.
   New: 4/9/20

8. **Question:** Can ground ambulance providers and suppliers report other services they provide

to PUI or COVID-19 patients?
Answer: Under §414.610(d), payment under the ambulance fee schedule represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements) for all services, supplies, and other costs for an ambulance transport service furnished to a Medicare beneficiary.
New: 4/9/20

9. **Question:** Can I consider any COVID-19 positive patient to meet the medical necessity requirements for ambulance transport?
   Answer: The medical necessity requirements for coverage of ambulance services have not been changed. For both emergency and non-emergency ambulance transportation, Medicare pays for ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other forms of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary.
   New: 4/9/20

10. **Question:** If the ambulance crew provides treatment but does not transport anyone, can the company bill Medicare for the services provided?
    Answer: No. Medicare law prohibits payment for an ambulance service unless a medically necessary transport of a Medicare beneficiary has taken place. However, when an enrolled physician or other qualified health professional furnishes services from an ambulance, he or she may bill for those services under the Medicare Physician Fee Schedule, assuming that the services furnished were in accordance with applicable state law and services are within his or her scope of practice requirements.
    Revised: 3/26/20

11. **Question:** How will ambulance services be paid when patients are moved from hospital to hospital or other approved locations?
    Answer: Medicare will pay for ambulance transportation according to the usual payment guidelines. Ambulance transportation charges for patients who were evacuated from and returned to originating hospitals should be included on the inpatient claims submitted by the originating hospitals. Payment will be included in the diagnostic related group (DRG) payment amounts made to hospitals paid under the prospective payment system.
    Revised: 3/26/20

12. **Question:** If a beneficiary who is living at home and using a stationary oxygen unit, has to be transported to another location by ambulance (because other means of transportation are contraindicated), can Medicare pay for any portable oxygen necessary to transport the beneficiary?

Answer: Medicare's standard payment to ambulance providers and suppliers under the Ambulance Fee Schedule for ambulance transports already includes payment for all necessary supplies, including oxygen, provided during the transport. Thus, if the transport is a Medicare-covered service (e.g., the beneficiary must be transported by ambulance to a covered destination because other means of transportation are contraindicated), then no separate payment for furnishing oxygen would be made.

However, if the transport does not qualify as a Medicare-covered service, then payment under Part B may be made to a Durable Medical Equipment supplier for furnishing portable oxygen when supplemental oxygen is needed for the beneficiary during the transport.
Revised: 3/26/20

13. **Question:** In emergency/disaster situations, how does CMS define an "approved destination" for ambulance transports and would it include alternate care centers, field hospitals and other facilities set up to provide patient care in response to the emergency/disaster?
Answer: CMS defines "approved destination" at 42 CFR 410.40(f), Origin and destination requirements. Medicare can only pay for ambulance transportation when it meets the origin and destination requirements and all other coverage requirements.

42 CFR 410.40(f) allows Medicare to pay for an ambulance transport (provided that transportation by any other means is contraindicated by the patient's condition and all other Medicare requirements are met) to the following destinations:

- From any point of origin to the nearest hospital, Critical Access Hospital (CAH), or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury and the return trip to the beneficiary's home. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.
- For beneficiaries residing in a SNF who are receiving Part B benefits only, ambulance transport from a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip. For SNF residents receiving Medicare Part A benefits, this type of ambulance service is subject to SNF consolidated billing.
- For a beneficiary who is receiving renal dialysis for treatment of ESRD, from a beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

A physician's office normally is not a covered destination under Medicare Part B. However, under certain circumstances an ambulance transport may temporarily stop at a physician's office without affecting the coverage status of the transport. Note that there is an exception

to this rule during the COVID-19 PHE, as explained further below.

Should a facility that would normally be the nearest appropriate facility be unavailable during an emergency/disaster, Medicare may pay for transportation to another facility so long as that facility meets all Medicare requirements and is still the nearest facility that is available and equipped to provide the needed care for the illness or injury involved.

Medicare payment for an ambulance transport to a temporary expansion site may be available if the site is determined to be part of a hospital, CAH or SNF that is an approved destination for an ambulance transport under 42 CFR 410.40(f). If the temporary expansion site is part of a hospital, CAH or SNF that is an approved destination under 42 CFR 410.40(f) for an ambulance transport, Medicare will pay for the transport on the same basis as it would to any other approved destination.

In addition, to provide ground ambulance providers and suppliers the flexibility to furnish medically necessary emergency and non-emergency ambulance transports for beneficiaries during the PHE for the COVID-19 pandemic, we are temporarily expanding the list of allowable destinations for ground ambulance transports. During the COVID-19 PHE, a covered destination for a ground ambulance transport may include any destination that is equipped to treat the condition of the patient in a manner consistent with state and local Emergency Medical Services (EMS) protocols in use where the services will be furnished. These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, CAH or SNF; community mental health centers; federally qualified health centers; rural health clinics, physician's offices; urgent care facilities; ambulatory surgical centers; any location furnishing dialysis services outside of the ESRD facility when an ESRD facility is not available; and the beneficiary's home. There must be a medically necessary ground ambulance transport of a patient in order for the ambulance service to be covered.

Physicians, non-physician practitioners, and suppliers should contact their Part B MAC or DME MAC with questions about SNF consolidated billing. There is also additional information about SNF consolidated billing on the CMS Medicare Learning Network (MLN) Publications webpage.

Institutional providers should contact their Part A MAC with questions about SNF consolidated billing. There is also additional information about SNF consolidated billing on the CMS MLN Publications webpage.
Revised: 4/10/20

14. Question: Our ambulance uses an electronic patient care reporting device to record beneficiary signatures that authorize submission of claims to Medicare. We are concerned

that a known or suspected COVID-19 patient using a touch screen to sign or holding an electronic pen or stylus could contaminate these devices for future patients and for ambulance personnel. Are we permitted to sign on behalf of a patient with known or suspected COVID-19?
Answer: Yes, but only under specific, limited circumstances. CMS will accept the signature of the ambulance provider's or supplier's transport staff if that beneficiary or an authorized representative gives verbal consent. CMS has determined that there is good cause to accept transport staff signatures under these circumstances. See 42 CFR 424.36(e). CMS recommends that ambulance providers and suppliers follow the Centers for Disease Control's Interim Guidance for Emergency Medical Services (EMS) Systems and 911 Public Safety Answering Points (PSAPs) for COVID-19 in the United States, which can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html. This guidance includes general guidelines for cleaning or maintaining EMS transport vehicles and equipment after transporting a patient with known or suspected COVID-19. However, in cases where it would not be possible or practical (such as a difficult to clean surface) to disinfect the electronic device after being touched by a beneficiary with known or suspected COVID-19, documentation should note the verbal consent.
New: 4/10/20

15. **Question:** Section 6002 of the Families First Coronavirus Response Act (FFCRA) removes cost-sharing under Medicare Part B (coinsurance and deductible amounts) for Medicare patients for certain COVID-19 testing-related services. CMS has issued billing guidance at: https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-04-07-mlnc-se under the "Families First Coronavirus Response Act Waives Coinsurance and Deductibles for Additional COVID-19 Related Services" heading. Is this applicable to ambulance services?
Answer: No. Section 6002 of the FFCRA does not apply to ambulance services. Section 6002 removes cost-sharing only for specified COVID-19 testing-related services which include only medical visits in certain categories of evaluation and management HCPCS codes, when payment is made to certain types of practitioners and facilities, which do not include ambulance providers and suppliers.
New: 6/16/20

16. **Question:** What requirements must be met to allow ground ambulance providers or suppliers to bill for services authorized through the waiver authority that was included in section 9832 of the American Rescue Plan Act of 2021?
Answer: The Secretary has authorized a waiver under this provision, and CMS has issued a blanket waiver to implement this provision, and has issued these FAQs. In order for the terms of the waiver to be met, the following conditions apply:
    1. The ground ambulance service was furnished in response to a 911 call (or the equivalent in areas without a 911 call system);

2. The Medicare beneficiary would have been transported to a destination permitted under Medicare regulations (as described in section 410.40 of title 42, Code of Federal Regulations (or successor regulations)) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the COVID-19 public health emergency;
3. The ground ambulance service would have met the existing Medicare ambulance services coverage criteria, such that, in the absence of a community-wide EMS protocol due to the COVID-19 public health emergency (PHE) that required or allowed certain transports to not be made, the beneficiary would have required medically necessary ground ambulance transport to the nearest appropriate facility able to treat the patient's condition and any other means of transportation would have been contraindicated;
4. The ground ambulance provider or supplier maintains, and can provide (upon request), documentation to support the need for the ground ambulance transport and the level of service provided and the documentation to support that a community-wide EMS protocol due to the COVID-19 PHE adequate to satisfy CMS's requirements (as specified in a separate FAQ) was in effect for the area at the time in which the ambulance treatment occurred; and
5. The service occurred on or after March 1, 2020.

Should all of the above criteria be met, and subject to any other applicable criteria including, but not limited to, review of medical necessity, Medicare will reimburse appropriately submitted claims under the Part B ambulance fee schedule based on the level of service that was provided: BLS emergency or ALS-1 emergency without mileage.

Should, however, the ambulance services be furnished by a Critical Access Hospital (CAH) or by an entity that is owned or operated by a CAH, payment would be made at 101 percent of reasonable costs, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. If there is no provider or supplier of ambulance services within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH. See section 1834(l)(8) of the Act, 42 CFR 413.70(b)(5)(D) and 100-04, Chapter 15, Section 10.4.

Importantly, payment under this waiver provision does NOT apply to a claim where:

1. The decision to not transport the patient was based solely on patient preference/decision, including when a patient refused transport "against medical advice"; or
2. The ambulance services would not have met Medicare's existing ambulance service medical necessity requirements (meaning the beneficiary would not have required medically necessary ground ambulance transport to the nearest appropriate facility able to treat the patient's condition and/or other means of transportation would not have been contraindicated).

New: 5/5/21

17. **Question:** Section 9832 of the American Rescue Plan Act of 2021 adds section 1135 waiver authority to permit Medicare payment to be made where a transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the COVID-19 public health emergency. For purposes of this provision, what are community-wide EMS protocols and what documentation does CMS require to pay for treatment in place during the COVID-19 pandemic under this waiver?
Answer: For purposes of applying this waiver, community-wide EMS protocols are those established by state, local, or municipal authorities (including by a hospital, but only where a hospital has the requisite legal authority) in response to the COVID-19 PHE that govern the provision of ambulance services, and that require or allow, with patient consent, an ambulance provider or supplier to "treat in place" a patient who otherwise, but for the COVID-19 PHE, would have been transported to a Medicare covered destination (such as a hospital). We believe that in most cases, such protocols were/will be issued in written format, and such format may have included, but is not limited to: state or local agency and official correspondence or electronic platforms that provided just-in-time updates to standard operative procedure or protocols. However, to the extent that a verbal protocol (such as from an individual hospital in a remote area) was/is in effect at the time of transport, we expect the verbal protocol to be fully documented. In addition, claims shall be submitted consistent with billing instructions, including the use of appropriate modifiers (for example, use of the 'CR' modifier is required to bill for claims under the waiver). Ambulance providers and suppliers must maintain documentation to support medical necessity and the qualifying community-wide EMS protocol, and, upon request, provide this to CMS contractors (that may use them for, among other things, part of medical review).
New: 5/5/21

18. **Question:** Does this waiver only apply to beneficiaries with COVID-19 or presumed to have COVID-19?
Answer: This waiver applies based on the criteria specified in the community-wide EMS protocol. Some protocols may be limited to patients with COVID-19 or presumed to have COVID-19, whereas we believe other protocols are/were not specific to the condition.
New: 5/5/21

19. **Question:** How do I submit a claim under the waiver?
    Answer: If the coverage requirements are met for a case in which an individual would have been transported to a covered destination but such transport did not occur as a result of community-wide EMS protocols due to the COVID-19 PHE, either HCPCS code A0429 (Ambulance service, basic life support, emergency transport (BLS-emergency) or A0427 (Ambulance service, advanced life support, emergency transport, level 1(ALS1)) based on the level of service provided, should be reported. No codes should be reported for mileage.

    In addition to reporting codes A0429 or A0427, 1) report a valid origin/destination modifier combination (in the first modifier position) that would have been appropriate had the beneficiary actually been transported, and 2) report the CR modifier. The CR modifier is required to facilitate a differentiation of these waiver claims from other claims, including claims for interventions covered under the Emergency, Triage, and Transport (ET3) model.

    Ambulance providers and suppliers may submit claims for services furnished on or after March 1, 2020.
    New: 5/5/21

20. **Question**: Will CMS waive beneficiary cost-sharing for ground ambulance services billed in accordance with the waiver during the COVID-19 pandemic?
    Answer: Under the Ambulance Fee Schedule, Medicare Part B pays 80 percent of the approved amount with the beneficiary responsible for 20 percent of the approved amount as well as the applicable Part B deductible. The HHS Office of Inspector General (OIG), however, has issued an FAQ explaining that waivers (or discounts) of beneficiary cost-sharing obligations incurred as a result of claims billed in accordance with this waiver represents a sufficiently low risk of fraud and abuse. To read OIG's FAQ, see https://oig.hhs.gov/coronavirus/authorities-faq.asp.
    New: 5/5/21

21. **Question**: Do mandatory claims submission rules apply?
    Answer: Yes. Unless ambulance providers and suppliers choose to furnish treatment in place services covered under the waiver without charge (that is, neither the individual furnished such items, nor anyone else, has a legal obligation to pay), they must submit claims to Medicare on behalf of the beneficiary.
    New: 5/5/21

22. **Question:** Does mandatory assignment apply to services covered under the waiver?
    Answer: Yes. Ambulance providers and suppliers must accept the Medicare allowed amount as payment in full and may not bill or collect from the beneficiary any amount other than the unmet deductible and coinsurance. If you previously charged a beneficiary for a service covered under the waiver, you must refund any amounts collected beyond the applicable

deductible and coinsurance. Violations of this requirement may subject the provider or supplier to sanctions.
New: 5/5/21

23. **Question**: How do I file claims that are more than 1 year old and are now covered under the waiver?
Answer: Under Medicare rules, claims must generally be submitted within 1 calendar year of the date of service. CMS exercised its authority under section 1135(b)(5) of the Act to modify the timetable for filing claims for services permissible under this waiver that were furnished between March 1, 2020 and May 5, 2021. The deadline to file claims that were not submitted within 12 months of the date of service is May 5, 2022. Ambulance providers and suppliers should include the "CR" modifier on the claim lines for the A0427 or A0429 base rate code, in addition to a valid origin/destination modifier combination indicating where the beneficiary would have been transported absent the qualifying community-wide EMS protocol when submitting claims, including for those claims with dates of service more than 1 year old. Ambulance providers and suppliers may submit claims in such a manner for services rendered on or after March 1, 2020. The normal timely filing deadline applies for services furnished after May 5, 2021.

    CMS notes that ambulance providers and suppliers must maintain documentation to support medical necessity of the services rendered and the presence of a qualifying community-wide EMS protocol, and, upon request, must provide such documentation to CMS contractors.
    New: 5/5/21

24. **Question**: Should a modified or reprocessed claim be submitted when a claim was processed using the QL modifier (patient pronounced dead after ambulance called)?
Answer: No. Ambulance providers and suppliers should continue to use the QL modifier when appropriate to report that the beneficiary died after dispatch, but before the beneficiary is loaded onboard the ambulance. The waiver does not supersede or change Medicare payment policy with respect to the QL modifier.
New: 5/5/21

25. **Question**: Does this provision (section 9832 of the American Rescue Plan Act of 2021) affect participation in the ET3 model?
Answer: No. ET3 Model participants are ambulance providers and suppliers that have been selected to participate in the model and have signed a participation agreement with CMS. Those ET3 model participants that have elected to implement the model's optional treatment in place intervention must enter into arrangements with qualified health care partners, which in turn must agree to furnish (or arrange for downstream practitioners to furnish) the model's treatment in place intervention. An ET3 Model participant that has

selected to implement the model's treatment in place intervention may still bill for initiating and facilitating treatment in place, and its qualified health care partners may still bill for furnishing treatment in place, under the ET3 Model. An ET3 Model participant is not prohibited from exercising the flexibility made available by the waiver under section 9832 of the American Rescue Plan Act of 2021, regardless of whether it elected to implement the ET3 model treatment in place intervention.
New: 5/5/21

26. **Question**: What is the impact of this waiver on coverage by Medicare Advantage Plans?
Answer: Medicare Advantage (MA) plans must provide coverage of, by furnishing, arranging for, or making payment for, all benefits that are covered under Part A and Part B in the FFS Medicare program, pursuant to section 1852(a) of the Act and 42 CFR §§ 422.100 and 422.101. Under the section 1135 waiver(s), authorized by the Secretary pursuant to section 9832 of the American Rescue Plan Act of 2021, of the requirement under sections 1861(s)(7) and 1834(l) of the Social Security Act that an ambulance service include the transport of an individual, the Medicare FFS program will pay for certain ambulance services where the individual was not transported under specific conditions. In order to fulfill its obligations under section 1852(a)(1) of the Act and §§ 422.100 and 422.101, an MA plan may not deny coverage based on the requirement that an ambulance service include the transport of the enrollee in situations where that requirement has been waived by CMS, as described in FAQs X through Y. We note that MA plans may continue to make appropriate medical necessity determinations using their own medical necessity criteria that are no more restrictive than original Medicare's national and, as applicable, local coverage policies.
New: 5/5/21

K. Ambulance Services- Vehicle and Staffing Requirements for Ambulance Providers and Suppliers

1. **Question:** Would a ground ambulance vehicle operating without a renewed license nevertheless satisfy the Medicare requirements at 42 CFR §410.41 if, during the PHE for the COVID-19 pandemic, a state or locality issues a law or regulation, or a legally adequate waiver, that permits ground ambulance vehicles to operate without a renewed license?
Answer: Yes, depending on state or local law. 42 CFR §410.41 specifies Medicare's requirements for ambulance vehicles, and §410.41(a)(1) states that a vehicle used as an ambulance must be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle. Key to this is that §410.41(a) requires compliance with state and local laws. During the PHE for the COVID-19 pandemic, should a state or locality enact or promulgate a law, regulation, or legally adequate waiver permitting an ambulance vehicle to operate without a renewed license, such an ambulance would be in compliance with Medicare's requirements at §410.41(a). We also note that the staffing requirements at §410.41(b) must be met in order for the ambulance transport to

meet the §410.41 requirements (see discussion in the FAQs below regarding waivers of these provisions).
New: 5/1/20

2. **Question:** During the PHE for the COVID-19 pandemic, if a state law or local law permits ambulance staffing by personnel licensed/certified below the levels of certification required under 42 CFR §410.41(b), would an ambulance so staffed be considered to meet the Medicare requirements of §410.41(b)? For example, CMS has heard that, during the course of the PHE for the COVID-19 pandemic, and pursuant to state waiver, one or more states may permit an Emergency Medical Responder (EMR), which is a certification status below the scope of practice of an Emergency Medical Technician (EMT) to staff a Basic Life Support (BLS) vehicle, or a Registered Nurse (RN), which is a health care professional status different than an EMT-paramedic, to staff an Advanced Life Support (ALS) vehicle.
   Answer: Yes, depending on state or local law. During the PHE for the COVID-19 pandemic, and pursuant to 42 U.S.C. 1320b-5(b)(1)(B), Medicare is waiving the specified ambulance staffing certification requirements of 42 CFR §410.41(b) such that, if a state and/or local law, or regulation, or a waiver issued by the applicable state or local authority permits a BLS or ALS ambulance to be alternatively staffed, such staffing arrangement would satisfy Medicare requirements. For example, should it be permitted by a state or local law, or regulation, or a waiver issued by the applicable state or local authority, for purposes of meeting Medicare's staffing requirements for a covered transport, a BLS vehicle could be staffed with an EMR instead of an EMT-basic or an ALS vehicle could be staffed with an RN instead of a EMT or paramedic. Note that the onus is on an ambulance provider or supplier to ensure that it otherwise continues to meet all applicable Medicare enrollment, coverage, and other requirements.
   New: 5/1/20

3. **Question:** During the PHE for the COVID-19 pandemic, if an ambulance provides services across state lines and the vehicle staff are not licensed or certified to provide services in the state in which the ambulance services are provided, will the ambulance be considered to meet the vehicle staff certification requirements under 42 CFR §410.41(b) while providing services in that state?
   Answer: During the PHE for the COVID-19 pandemic, pursuant to 42 U.S.C. 1320b-5(b)(2), Medicare is waiving the requirement at 42 CFR §410.41(b) that vehicle personnel be licensed or certified in the State in which they are furnishing services if they have equivalent licensing or certification in another State and are not affirmatively excluded from practice in that State or in any other State. Where the terms of this waiver are met, the ambulance staff certification requirements of §410.41(b) could be met when ambulances provide services across state lines. Note, however, that this does not waive state or local laws (only Medicare's own certification requirements in §410.41(b) for purposes of Medicare payment and coverage) such that, should a state not permit out of state ambulances to provide

services, Medicare's waiver would not affect a state's potential enforcement of its provisions.
New: 5/1/20

L. Ambulance: Data Collection and Reporting Requirements for the Medicare Ground Ambulance Data Collection System

1. **Question:** CMS requires selected ground ambulance organizations to collect cost, revenue, utilization, and other information through the Medicare Ground Ambulance Data Collection System. The collected information will be provided to MedPAC, which is required to submit a report to Congress on the adequacy of Medicare payment rates for ground ambulance services and geographic variations in the cost of furnishing such services. Will the data collection and reporting requirements for the Medicare Ground Ambulance Data Collection System be delayed due to COVID-19?
   Answer: Yes. CMS has issued a revised blanket waiver: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf due to the public health emergency (PHE) for the COVID-19 pandemic. CMS is modifying the data collection period and data reporting period, as defined at 42 CFR §414.626(a), for ground ambulance organizations that were selected by CMS to collect data beginning between January 1, 2020, and December 31, 2020 (Year 1) and for ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2).

   Under this modification, these ground ambulance organizations can select a new data collection period that begins between January 1, 2022, and December 31, 2022; collect the necessary data during their selected data collection period; and submit the data during the data-reporting period that corresponds to their selected data collection period.

   CMS is modifying this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020–2021 so that they can focus on their operations in support of patient care.

   For additional information on the Medicare Ground Ambulance Data Collection System, please visit the Ambulances Services Center website at https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.
   Updated: 2/7/21

2. **Question:** Will the 10 percent payment reduction still apply to ground ambulance organizations that are now required to collect and report data under the modified data collection and reporting period but do not sufficiently report the required data?

Answer: Yes. The 10 percent payment reduction described at 42 CFR §414.610(c)(9) will still apply if a ground ambulance organization is selected to collect and report data under the modified data collection and reporting timeframe, but does not sufficiently submit the required data according to the modified timeframe and is not granted a hardship exemption. The payment reduction will be applied to payments made under the Medicare Part B Ambulance Fee Schedule for services furnished during the calendar year that begins following the date that CMS provides written notification that the ground ambulance organization did not submit the required data.
New: 6/16/20

3. **Question:** The modification states that the ground ambulance organizations that were selected by CMS to collect data beginning between January 1, 2020, and December 31, 2020 (year 1) and ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) can select a new continuous 12-month data collection period that begins between January 1, 2022, and December 31, 2022. Do the ground ambulance organizations that were selected in year 1 have an option to continue with their current data collection period or choose to select a new data collection period starting in 2022?
   Answer: No. The ground ambulance organizations that were selected for year 1 and year 2 must select a new data collection period that begins in 2022. CMS will not allow ground ambulance organizations the option to continue with their current data collection period because the data collected in 2020 and 2021 during the PHE may not be reflective of typical costs and revenue associated with providing ground ambulance services.
   Updated: 2/7/21

4. **Question:** Does the guidance mean that the data collected starting in 2022 by the selected ground ambulance organizations for year 1, year 2, and year 3 will not be reported to CMS until 2023-2024 and that both the ground ambulance organizations that were selected for year 1 and the ground ambulance organizations that will be selected for year 2 will collect and report data during the same time periods?
   Answer: Yes. Under the modification, ground ambulance organizations that were selected for year 1 will not collect data in 2020 and ground ambulance organizations that were selected in year 2 will not collect data in 2021. These ground ambulance organizations will select a new data collection period that begins in 2022 and must submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. As a result of the modification, year 1, year 2, and year 3 selected ground ambulance organizations will collect and report data during the same time periods.
   Updated: 2/7/21

M. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. **Question:** Has CMS implemented any changes to help RHCs and FQHCs respond to the to the serious public health threats posed by the spread of the 2019 novel coronavirus (COVID-19)?
   Answer: Yes. CMS has removed some regulatory requirements and added additional flexibilities to assist RHCs and FQHCs in furnishing services during the COVID-19 Public Health Emergency (PHE). These include:
   a) Expansion of Virtual Communication Services for RHCs and FQHCs to include online digital evaluation and management services using patient portals; and
   b) Revision of Home Health Agency Shortage Area Requirement for Visiting Nursing Services Furnished by RHCs and FQHCs

   New: 4/9/20

2. **Question:** When do these changes go into effect?
   Answer: These changes are in effect for the duration of the COVID-19 PHE and are not permanent.
   New: 4/9/20

3. **Question:** Are these changes permanent?
   Answer: These changes are in effect for the duration of the PHE for the COVID-19 pandemic and are not permanent.
   New: 4/9/20

4. **Question:** Do these changes apply to all RHCs and FQHCs?
   Answer: Yes. They apply to all RHCs (independent/freestanding and provider-based) and all FQHCs (including grandfathered tribal FQHCs).
   New: 4/9/20

5. **Question:** Can a mental health visit be furnished as a distant site telehealth service?
   Answer: Yes. A mental health visit can be furnished as a distant site telehealth service for the duration of the COVID-19 PHE. For a list of services that can be furnished via Telehealth, please see https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
   New: 6/16/20

6. **Question:** Can a medical visit and a mental health visit be reported on the same day when furnished as a distant site telehealth service?
   Answer: Yes. A medical visit and a mental health visit can be furnished on the same day as distant site telehealth services for the duration of the COVID-19 PHE.

New: 6/16/20

7. **Question:** How do we report distant site telehealth services when a mental health visit is furnished on the same day as a medical visit?
   Answer: Distant site Telehealth services should be billed with HCPCS code G2025 and the appropriate revenue code, 052X for a medical visit or 0900 for mental health. Please see SE20016 for billing guidance, available at https://www.cms.gov/files/document/se20016.pdf.
   New: 6/16/20

8. **Question:** What if the mental health visit code is not on the FQHC qualifying visit list?
   Answer: If a mental health visit code is not currently on the FQHC qualifying visit list, then those claims should be held until July 1, 2020. If the mental health visit code is on the FQHC qualifying list, then you can submit the claim before July 1, 2020. Please see SE20016 for additional billing guidance. https://www.cms.gov/files/document/se20016.pdf
   New: 6/16/20

9. **Question:** Which health care providers are permitted to furnish distant site telehealth services for RHCs and FQHCs during the COVID-19 PHE?
   Answer: The health care providers that are currently authorized to furnish primary care services in RHCs and FQHCs are permitted to furnish distant site telehealth services under the waiver authority during the COVID-19 PHE, including physicians and certain non-physician practitioners such as nurse practitioners, physician assistants and certified nurse midwives. Other practitioners, such as certified nurse anesthetists, licensed clinical social workers, clinical psychologists, and registered dietitians or nutrition professionals may also furnish telehealth services within their scope of practice and consistent with Medicare benefit rules that apply to all services.
   New: 6/16/20

10. **Question:** Are there changes to the direct supervision requirements for RHCs and FQHCs?
    Answer: In general, the requirements for direct supervision have been modified for the duration of the COVID-19 PHE to include the use of a virtual supervisory presence through the use of interactive audio and video telecommunications technology.
    New: 6/16/20

11. **Question**: Is a specimen collection separately payable in an RHC or FQHC?
    Answer: Specimen collection services are included in the all-inclusive rate for RHCs and the prospective payment system for FQHCs and are not paid separately, including a specimen collection for COVID-19 testing.
    New: 6/16/20

12. **Question:** If a hospital increases the number of beds during the COVID-19 PHE, will a provider-based RHC lose its exemption to the payment limit if the hospital has more than 50 beds?
Answer: Generally, RHCs that are provider-based to a hospital with fewer than 50 beds are exempt from the national RHC payment limit per Section 1833(f) of the Social Security Act. For the duration of the PHE, we are implementing, on an interim basis, a change to the period of time used to determine the number of beds in a hospital at § 412.105(b) for purposes of determining which provider-based RHCs are subject to the payment limit. For the duration of the PHE, we will use the number of beds from the cost-reporting period prior to the start of the PHE as the official hospital bed count for application of this policy. Allowing for these provider-based RHCs to continue to receive the payment amounts they would otherwise receive in the absence of the PHE will help maintain their ability to provide necessary health care services to underserved communities.
New: 6/19/20

13. **Question:** Can RHCs and FQHCs furnish and bill for telehealth services?
Answer: During the COVID-19 PHE, RHCs and FQHCs can furnish any telehealth service that is included on the list of Medicare telehealth services under the Physician Fee Schedule (PFS). Telehealth services generally require use of interactive real-time audio and video technology. However, during the PHE, some services can be furnished using audio technology only. RHCs and FQHCs can furnish and bill for the services on the list of Medicare telehealth services using HCPCS code G2025. Payment to RHCs and FQHCs for distant site telehealth services is set at $92.03, which is the average amount for all PFS telehealth services on the telehealth list, weighted by volume for those services reported under the PFS. Please also refer to https://www.cms.gov/files/document/se20016.pdf
New: 6/19/20

14. **Question:** Which telehealth services can RHCs and FQHCs furnish and bill for when furnished using audio technology only?
Answer: During the COVID-19 PHE, RHCs and FQHCs can furnish any telehealth service that is included on the list of Medicare telehealth services under the Physician Fee Schedule (PFS), and bill for it using HCPCS code G2025. Several codes on the Medicare telehealth list describe telephone evaluation and management (E/M) services (CPT codes 99441-99443), and CMS has used waiver authority to allow some behavioral health and patient education services to be furnished using audio-only technology. These services are included on the Medicare telehealth list which can be found at this website: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time, interactive communication between the patient and distant site physician or practitioner.

New: 6/19/20

15. **Question:** What are the requirements for RHCs and FQHCs billing telephone E/M services?
Answer: Telephone E/M services (as described by CPT codes 99441-99443) have been added to the Medicare telehealth services list effective March 1. RHCs and FQHCs can bill for the services described by these codes as they do other Medicare telehealth services using HCPCS code G2025, taking into consideration the CPT code description for the services. To bill for telephone E/M services, at least 5 minutes of medical discussion for a telephone E/M service by a physician or other qualified health care professional who may report E/M services must be provided to a patient, parent, or guardian. These services cannot be billed if they originate from a related E/M service provided within the previous 7 days or lead to another E/M service or a procedure within the next 24 hours or the soonest available appointment, including a service furnished via telehealth. CMS will exercise its enforcement discretion to not impose penalties so that these services may also be furnished to new patients in addition to established patients, during the PHE.
New: 6/19/20

N. Expansion of Virtual Communication Services for FQHCs/RHCs

1. **Question:** What are "online digital evaluation and management services" in RHCs and FQHCs?
Answer: Online digital evaluation and management services are non-face-to face, patient-initiated, digital communications using a patient portal, that require a clinical decision that otherwise typically would have been provided in the office. CMS has been paying separately under the physician fee schedule for these services since before the PHE and is expanding the same flexibilities to RHCs and FQHCs.
New: 4/9/20

2. **Question:** Are there specific codes that describe these services?
Answer: Yes. The codes that have been added for RHCs and FQHCs are:
    - 99421 - Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
    - 99422 - Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes
    - 99423 - Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.
    New: 4/9/20

3. **Question:** What is an online patient portal?
Answer: An online patient portal is a secure online website that gives patients 24-hour access to personal health information from anywhere with an Internet connection by

using a secure username and password.
New: 4/9/20

4. **Questions:** Does the RHC or FQHC practitioner have to be physically in the RHC or FQHC, or can they respond from another location such as their home?
   Answer: The RHC or FQHC practitioner can respond from any location during a time that they are scheduled to work for the RHC or FQHC.
   New: 4/9/20

5. **Question:** How will Medicare pay RHCs and FQHCs for performing online digital evaluation and management services?
   Answer: The online digital assessment codes are being added to the codes that are billed using HCPCS code G0071, the RHC/FQHC specific code for Virtual Communication Services.
   New: 4/9/20

6. **Question:** How can RHCs and FQHCs bill for online digital evaluation and management services?
   Answer: RHCs and FQHCs can bill for online digital evaluation and management services using the RHC/FQHC HCPCS code G0071. The payment for G0071 will be the PFS national non-facility payment rate for HCPCS code G2012 (communication technology-based services), HCPCS code G2010 (remote evaluation services), CPT 99421, CPT 99422, and CPT 99423. The new payment rate is $24.76.
   New: 4/9/20

7. **Question:** When will the new payment rate for G0071 be effective?
   Answer: The new payment rate is effective for services provided on or after March 1, 2020. However, claims submitted with this code before the claims processing system is updated will be reprocessed.
   New: 4/9/20

8. **Question:** How frequently can G0071 be billed by RHCs and FQHCs?
   Answer: Because these codes are for a minimum 7-day period of time, they cannot be billed more than once every 7 days.
   New: 4/9/20

9. **Question:** Can virtual communication services be furnished to both new and established patients?
   Answer: Yes. Virtual communication services may be furnished to both new and established patients during the COVID-19 PHE.
   New: 4/9/20

10. **Question:** Is beneficiary consent required?
    Answer: Yes, but during the PHE, it may be obtained at the same time the services are furnished.
    New: 4/9/20

11. **Question**: Will RHCs be held to the RHC productivity requirements during the COVID-19 PHE?
    Answer: Many RHCs have had to change the way they staff their clinics and bill for RHC services as a result of the COVID-19 PHE and may have difficulty in meeting the productivity standards. Under existing policy in Chapter 13 of the Medicare Benefit Policy Manual, A/B MACs can provide an exception to any RHC that has had difficulty in meeting the productivity standards as a result of the COVID-19 PHE; A/B MACs may choose to proactively grant productivity exceptions to RHCs who have experienced disruptions in staffing and services as a result of the COVID-19 PHE.
    New: 5/27/2020

12. **Question**: What telehealth services can be furnished and billed by RHCs and FQHCs?
    Answer: RHCs and FQHCs can serve as the distant site to furnish and bill for any telehealth services that are included on the list of Medicare telehealth services under the Physician Fee Schedule (PFS) for the duration of the COVID-19 PHE. A list of this services can be found here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
    New: 5/27/2020

13. **Question**: How should distant site telehealth services be reported on the cost report?
    Answer: RHCs and FQHCs should report distant site telehealth service costs on their cost report along with costs for furnishing originating site telehealth services. RHCs must report both originating and distant site telehealth costs on Form CMS-222-17 on line 79 of the Worksheet A, in the section titled “Cost Other Than RHC Services.” FQHCs must report both originating and distant site telehealth costs on Form CMS-224-14, the Federally Qualified Health Center Cost Report, on line 66 of the Worksheet A, in the section titled “Other FQHC Services”.
    New: 5/27/2020

14. **Question**: Do distant site telehealth services have to be related to COVID-19?
    Answer: No. Distant site telehealth services do not have to be related to COVID-19.
    New: 5/27/2020

15. **Question**: Do telehealth services have to be initiated by the patient?
    Answer: No. Telehealth services do not have to be initiated by the patient. However, the patient should be made aware of any cost-sharing for which he or she is liable.

New: 5/27/2020

16. **Question**: Who can furnish distant site telehealth services?
    Answer: Distant site telehealth services can be furnished by the RHC or FQHC practitioner or any health care practitioner working within their state scope of practice. They have to be working for the RHC/FQHC, as an employee or under direct contract.
    New: 5/27/2020

17. **Question**: Where can RHC or FQHC practitioners be located when furnishing distant site telehealth services?
    Answer: For the duration of the COVID-19 PHE, RHC or FQHC practitioners can furnish distant site telehealth services from any location, including their home, during the time that they are working for the RHC or FQHC.
    New: 5/27/2020

18. **Question**: Can the patient's home serve as an originating site?
    Answer: Yes. Effective March 6, 2020, the patient's home can serve an originating site for the duration of the COVID-19 PHE. For treatment of substance use disorder and related conditions, the patient's home was eligible before the PHE.
    New: 5/27/2020

19. **Question**: Will coinsurance apply to distant site telehealth services?
    Answer: During the COVID-19 PHE, coinsurance and deductible (if applicable) does not apply for certain evaluation and management services when they are related to COVID-19 testing, whether they are furnished in person or via telehealth. A list of these services can be found at https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-04-07-mlnc-se#_Toc37139913. Additional information regarding coinsurance and deductibles can be found at https://www.cms.gov/files/document/se20011.pdf.
    New: 5/27/2020

20. **Question**: Are modifiers required to identify services to which coinsurance and deductibles do not apply?
    Answer: RHCs and FQHCs must use the "CS" modifier on the claim to identify the COVID-19 testing-related services to which the coinsurance and deductible do not apply. Coinsurance and deductible amounts should not be collected from beneficiaries for these services.
    New: 5/27/2020

21. **Question**: Will coinsurance and deductibles apply for telehealth services that are not related to COVID-19 testing?
    Answer: Yes. Coinsurance and deductible (if applicable) is only removed for specified

COVID-19 testing-related services, whether they are furnished in person or via telehealth, as described at https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-04-07-mlnc-se.
New: 5/27/2020

22. **Question**: Can FQHC lookalikes also bill for distant site telehealth services during the COVID-19 PHE?
Answer: Yes, FQHC lookalikes can also bill for distant site telehealth services for the duration of the COVID-19 PHE.
New: 5/27/2020

23. **Question**: When did the changes for services furnished by RHCs and FQHCs during the COVID-19 PHE go into effect?
Answer: The effective dates for these changes are as follows:
Distant Site Telehealth Services by RHCs and FQHCs - January 27, 2020
Telehealth Services Furnished when the patient is at home - March 6, 2020 (For treatment of substance use disorder and related conditions, the patient's home was eligible before the PHE).
Expanded Virtual Communication Services - March 1, 2020
Revision of HHA Shortage Area Requirement for Visiting Nursing Services - March 1, 2020
Audio-only Telehealth Services - March 1, 2020
New: 5/27/2020

O. Revision of the Home Health Agency Shortage Area Requirement for Visiting Nursing Services Furnished by RHCs and FQHCs

1. **Question:** Can RHCs and FQHCs bill for visiting nursing services?
Answer: Yes. In an area in which there exists a shortage of home health agencies (HHAs), visiting nursing services can be furnished to a homebound individual by an RN or a LPN under a written plan of treatment.
New: 4/9/20

2. **Question:** How are we changing the HHA shortage area requirement for visiting nursing services and what additional flexibilities does this provide for RHCs and FQHCs?
Answer: During the COVID-19 PHE, we will assume that the area typically served by the RHC, and the area that is included in the FQHC's service area plan, has a shortage of home health agencies, and no request for this determination is required. The RHC or FQHCs must check the HIPAA Eligibility Transaction System (HETS) before providing visiting nurse services to ensure that the patient is not already under a home health plan of care. No visits will be payable to the RHC/FQHC if such patient is already being treated under a home health plan of care.

New: 4/9/20

3. **Question:** Is there a change in how "homebound" is determined?
   Answer: No. During the PHE, as previously, a patient would be considered "homebound" if it is medically contraindicated for the patient to leave the home. The patient's medical records must document leaving the home is medically contraindicated. For example, a beneficiary could be considered "homebound" if: (1) a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.
   New: 4/9/20

4. **Question:** Can a visiting nurse service be billed if the nurse goes to the patient's home to collect a lab specimen for coronavirus testing?
   Answer: Not if it is the only service provided. Visiting nurse services are only billable as an RHC/FQHC visit when they require skilled nursing services. If the RN or LPN collects a specimen for testing and does not provide skilled nursing services under a written plan of treatment, then it would not be a RHC or FQHC billable visit.
   New: 4/9/20

5. **Question:** How does this change affect how RHCs and FQHCs bill for visiting nursing services?
   Answer: There are no billing changes for visiting nursing services. Qualified visiting nursing services are billed as an RHC or FQHC visit using revenue code 0527.
   New: 4/9/20

P. Medicare Telehealth

1. **Question:** What services can be provided by telehealth during a waiver for the public health emergency (PHE) declared by the Secretary under the section 1135 waiver authority?
   Answer: Medicare telehealth services include many services that are normally furnished in-person. CMS maintains a list of services that may be furnished via Medicare telehealth. This list is available here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. These services are described by HCPCS codes and paid under the Physician Fee Schedule. Under the emergency declaration and waivers, these services may be provided to patients by physicians and certain non-physician practitioners regardless of the patient's location. Medicare also pays for certain other services that are commonly furnished remotely using telecommunications technology, but are not considered Medicare telehealth services. These services can always be provided to patients wherever they are located, and include physician interpretation of diagnostic

tests, care management services, and virtual check-ins.
New: 4/9/20

2. **Question:** What types of health care practitioners are permitted to furnish telehealth services under broadened 1135 waiver authority granted by the CARES Act?
Answer: All health care practitioners who are authorized to bill Medicare for their professional services may also furnish and bill for telehealth services. This allows health care professionals who were not previously authorized under the statute to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.

   Additionally, telehealth services performed by auxiliary personnel who cannot independently bill Medicare for their services, such as respiratory therapists, can be furnished and billed incident to the services of an eligible billing practitioner.

   Hospitals do not bill for Medicare telehealth services. However, if a hospital employs certain practitioners who are not authorized to independently bill Medicare for their services, such as respiratory therapists, the hospital may bill for the outpatient hospital services provided by that staff using telecommunications technology. Hospitals should review requirements for providing hospital services in relocated provider based departments including the patient's home and temporary expansion locations as appropriate. We note that Medicare cannot pay for services that are furnished by a physician or practitioner located outside of the United States (see 42 CFR 411.9).
   Updated: 6/19/20

3. **Question:** Is any specialized equipment needed to furnish Medicare telehealth services?
Answer: Currently, CMS requires most telehealth services to be furnished using telecommunications technology that has audio and video capabilities that are used for two-way, real-time interactive communication. For example, to the extent that many mobile computing devices have audio and video capabilities that may be used for two-way, real-time interactive communication, they may be used to furnish Medicare telehealth services.

   CMS has used its waiver authority to allow, beginning on March 1, 2020, telephone evaluation and management codes and certain counseling behavioral health care and educational services, to be furnished as telehealth services using audio-only communications technology (telephones or other audio-only devices). A list of those services is available here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. For all other services, a Medicare telehealth service requires, at a minimum, audio and video equipment permitting two-way, real-time

interactive communication between the patient and distant site physician or practitioner. Update: 6/19/20

4. **Question:** Can practitioners provide Medicare telehealth services using video-enabled phones?
   Answer: Yes. CMS amended its regulations to remove outdated references that could be interpreted as potential restrictions on technology that practitioners can use to provide telehealth services. Interactive real-time audio-video technology may be used to perform all services on the Medicare telehealth list.

   The HHS Office for Civil Rights has issued a Notification of Enforcement Discretion and related guidance to ensure that covered health care providers can use popular non-public facing applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype, to provide telehealth without risk of penalty for noncompliance with the HIPAA Rules related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency. For more information on the Office for Civil Rights' guidance, please visit; https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html; and https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf

   CMS has used its waiver authority to allow, beginning on March 1, 2020, telephone evaluation and management codes and certain behavioral health care and educational services to be furnished via telehealth using audio-only telephones. A complete list of Medicare telehealth services, including those that may be furnished using audio-only technology, is available here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

   For the duration of the PHE for the COVID-19 pandemic, Medicare is making payment for CPT codes 99441–99443, which describe an audio-only phone visit for practitioners who can independently bill for E/M services. These CPT codes can be used for both new and established patients. As for all Medicare telehealth services furnished during the PHE, please report the place of service code that would have applied if the service had occurred in person for these telephone-only telehealth service codes.

   Medicare payment rates for audio-only telephone evaluation and management visits are aligned with the payment rates for the established patient office/outpatient E/M visit levels 2–4 (CPT codes 99212–99214). Claims processed at the lower rate before the payment changes are in place will be automatically re-processed by Medicare Administrative Contractors.

In addition, while CMS did not add the codes to the Medicare telehealth services list, during the PHE for COVID-19, CMS makes separate payment for CPT codes 98966–98968, which describe audio-only telephone assessment and management visits with health care practitioners who cannot independently bill for E/M phone visits, for example certain therapists, social workers, and clinical psychologists.
Updated: 6/19/20

5. **Question:** How does a health care provider bill for telehealth services?
   Answer: The IFC directs physicians and practitioners who bill for Medicare telehealth services to report the place of service (POS) code that would have been reported had the service been furnished in person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the PHE for the COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. We believe this interim change will maintain overall relativity under the PFS for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth. During the PHE, the CPT telehealth modifier, modifier 95, should be applied to claim lines that describe services furnished via telehealth. Practitioners should continue to bill these services using the CMS-1500/837P.
   New: 4/9/20

6. **Question:** How much does Medicare pay for telehealth services?
   Answer: Medicare pays the same amount for telehealth services as it would if the service were furnished in person.
   New: 4/9/20

7. **Question:** How long will practitioners be able to bill using these new flexibilities?
   Answer: The telehealth waiver will be effective until the end of the PHE declared by the Secretary of HHS on January 31, 2020. Billing for the expanded Medicare telehealth services, as well as for the telephone assessment and management, telephone, evaluation and management services, and additional flexibilities for communications technology-based services (CTBS) are effective beginning March 1, 2020, and through the end of the PHE.
   New: 4/9/20

8. **Question:** Can physicians and practitioners let their patients know that Medicare covers telehealth in new locations during the PHE?
   Answer: Yes. Physicians and practitioners should inform their patients that services are available via telehealth in new locations, including their homes, during the PHE and educate them on any applicable cost sharing.
   New: 4/9/20

9. **Question:** Should on-site visits conducted via video or through a window in the clinic suite be reported as telehealth services? How could a physician or practitioner bill if this were telehealth?
   Answer: Services should only be reported as telehealth services when the individual physician or practitioner furnishing the service is not at the same location as the beneficiary. If the physician or practitioner furnished the service from a place other than where the beneficiary is located (a "distant site"), they should report those services as telehealth services. If the beneficiary and the physician or practitioner furnishing the service are in the same institutional setting but are utilizing telecommunications technology to furnish the service due to exposure risks, the practitioner would not need to report this service as telehealth and should instead report whatever code described the in-person service furnished.
   New: 4/9/20

10. **Question:** How are telehealth services different from virtual check-ins and e-visits? How much does Medicare pay for these services?
    Answer: Medicare telehealth services are services that would normally occur in person but are instead conducted via telecommunications technology and are paid at the full in-person rate. Service such as the virtual check-in, eVisits, remote evaluation, and telephone visits are not services that would normally occur in person, and are not paid as though the service occurred in person. A virtual check-in lets professionals bill for brief (5-10 min) communications that mitigate the need for an in-person visit and can be furnished via any synchronous telecommunications technology visit that would be furnished along with an e-visit is similar to a virtual check-in, but should be reported when a beneficiary communicates with their health care provider through an online patient portal. Telephone visits may be furnished via audio-only telephone whereas the remote evaluation describes the evaluation of a prerecorded video or image provided by the patient. Table 1 illustrates the respective payment rates to the physician or other practitioner; they vary based on the practice setting.
    New: 4/9/20

Table 1: Payment rates for the virtual check in and the e-Visit

HCPCS	Descriptor	Office-based Payment Rate to the Professional	Facility-based Payment Rate to the Professional
99421	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	$15.52	$13.35

HCPCS	Descriptor	Office-based Payment Rate to the Professional	Facility-based Payment Rate to the Professional
99422	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	$31.04	$27.43
99423	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	$50.16	$43.67
G2061	Qualified non-physician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes	$12.27	$12.27
G2062	Qualified non-physician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes	$21.65	$21.65
G2063	Qualified non-physician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes	$33.92	$33.56
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	$14.80	$13.35

11. Question: What has changed for communication technology-based services (e.g. remote evaluation of patient images/video and virtual check-in) for practitioners who bill for E/M codes?

Answer: During the PHE for COVID-19, HCPCS codes G2010 and G2012, which may only be reported when they do not result in an in-person or telehealth visit, can be furnished to

both new and established patients. During the PHE, the required annual beneficiary consent to receive these services may be obtained at the same time that the services are furnished either by the billing practitioner or by staff under general supervision. If the brief communication technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional the service would be considered bundled into the previous E/M service and would not be separately billable.
New: 4/9/20

12. **Question:** Can other practitioners who do not bill for E/M codes provide communication technology-based services (e.g. remote evaluation of patient images/video and virtual check-in) or telephone assessment and management services during the PHE?
Answer: Yes. During the PHE, the availability of HCPCS codes G2010 and G2012 is broadened to allow certain practitioners, such as physical therapists, occupational therapists, speech language pathologists, licensed clinical social workers, and clinical psychologists, who do not report E/M codes to bill for these services. CMS has also activated CPT codes 98966, 98967, and 98968, which describe assessment and management services conducted over the phone.
New: 4/9/20

13. **Question:** Will CMS require specific modifiers to be applied to the existing codes?
Answer: For telehealth services furnished during the PHE, CMS is allowing practitioners to use the POS code that they would have otherwise reported had the service been furnished in person. To identify these services as Medicare telehealth, CMS is requiring that modifier 95 be appended to the claim.

    There are also three additional scenarios where modifiers are ordinarily required on Medicare telehealth claims. When a telehealth service is furnished via asynchronous (store and forward) technology as part of a federal telemedicine demonstration project in Alaska and Hawaii, the GQ modifier is required. When a telehealth service is billed under CAH Method II, the GT modifier is required. Finally, when telehealth service is furnished for purposes of diagnosis and treatment of an acute stroke, the G0 modifier is required.
    New: 4/9/20

14. **Question:** Can the distant site practitioner furnish Medicare telehealth services from their home? Or do they have to be in a medical facility?
Answer: There are no payment restrictions on distant site practitioners furnishing Medicare telehealth services from their home during the public health emergency. The practitioner should report the place of service (POS) code that would have been reported had the service been furnished in person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the PHE for the

COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person.
New: 4/9/20

15. **Question:** What about beneficiaries who do not have access to smart phones or other technology that supports two-way, audio and video telecommunications technology or patients that do not want to use video?
Answer: Beginning on March 1, 2020, health care providers can bill certain Medicare telehealth services furnished via audio-only calls, including telephone evaluation and management services, and specific behavioral health care and educational services. These services may be billed for both new and established patients.
New: 6/19/20

16. **Question:** What has changed for communication technology-based services (CTBS) (HCPCS codes G2010 and G2012 - e.g. remote evaluation of patient images/video and virtual check-ins) for practitioners who bill for Evaluation and Management (E/M) services?
Answer: As stated in the CY 2019 PFS final rule, we finalized that if the communications technology-based service originates from a related E/M service provided within the previous 7 days by the same physician or other qualified health care professional, the CTBS would be considered bundled into that previous E/M service and would not be separately billable. Under the policy in the CY 2019 PFS final rule, in instances when the CTBS leads to an E/M service with the same physician or other qualified health care professional, the CTBS is considered bundled into the pre- or post-visit time of the associated E/M service, and therefore, would not be separately billable. However, when the CTBS leads to an E/M visit with a different physician or other qualified health care professional, the CTBS would not be considered bundled into that visit (83 FR 59486) and the CTBS is separately billable. This has not changed during the PHE.
New: 4/9/20

17. **Question:** Can consent for multiple CTBS or interprofessional consultations services be obtained at one time?
Answer: Yes. Beneficiary consent may be obtained annually for all CTBS (e.g. remote evaluation of patient images/video and virtual check-ins) or interprofessional consultation services occurring within the year (84 FR 62699).
New: 4/9/20

18. **Question:** What does it mean for CTBS (HCPCS codes G2010 and G2012, (e.g. remote evaluation of patient images/video and virtual check-ins)) to be initiated by the patient?
Answer: On page 59484 of the CY 2019 PFS final rule, we stated that, for G2012, “We expect that these services will be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services.” For

G2010, we noted that this service is initiated by the patient (83 FR 59487). This means that the patient must consent to the service before or at the same it takes place and does not prohibit practitioners from educating, on their own initiative, beneficiaries on the availability of the service prior to, or at the same time it takes place.
New: 4/9/20

19. **Question:** Can the CTBS (HCPCS codes G2010 and G2012, (e.g. remote evaluation of patient images/video and virtual check-ins)) be billed on the same day, by the same practitioner, for the same patient?
Answer: As long as all requirements for billing both codes are met, and time and effort are not being counted twice, HCPCS codes G2010 and G2012 may be billed by the same practitioner, for the same patient, on the same day.
New: 4/9/20

20. **Question:** Can Remote Physiologic Monitoring (RPM) services be furnished to new patients as well as established patients?
Answer: Starting March 1 and for the duration of the PHE, RPM services can be furnished to both new and established patients. We ordinarily require an initiating visit for RPM services, similar to other care management services, but this requirement may be satisfied via a telehealth visit. Regardless, for the duration of the PHE, we are not requiring patients to be established patients in order to receive RPM services. Patients that receive RPM services can be established or new.
Revised: 4/23/20

21. **Question:** May clinical staff provide RPM services under general supervision?
Answer: Yes. We finalized in the CY 2020 PFS final rule (84 FR 62698) that RPM services, including but not limited to HCPCS codes 99453, 99454, 99457, 99458, may be provided under the general supervision of the billing practitioner. We note that, beneficiary consent to receive these services may also be obtained by auxiliary personnel under general supervision of the billing practitioner. Further, we note that, as specified in the IFC (85 FR 19245-19246), during the PHE when physicians and other health care professionals are faced with challenges regarding potential exposure risks for themselves and their patients, the direct supervision requirement that applies for most other services that are furnished incident to a physician or other practitioner's services may be met virtually through audio/video real-time communications technology.

    We also note that clinical staff are "auxiliary personnel." According to the 2019 CPT Codebook (p. xii), "A clinical staff member is a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report that professional service."

New: 4/9/20

22. **Question:** The prefatory language for the Remote Physiologic Monitoring (RPM) CPT codes 99453, 99454, and 99457 requires that the device used to capture a patient's physiologic data must be a medical device as defined by the FDA. Can we assume that any device used to capture a patient's physiologic data whether Class I, Class II, Class III would meet this requirement?
Answer: The device used to capture a patient's physiologic data must meet the FDA definition of being a medical device. The CPT code descriptor does not indicate that the device must be an FDA approved device. Medical devices are defined on the FDA website as follows:
"Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines, and medical lasers." For more information, see the FDA link at: https://www.fda.gov/medical-devices.
New: 4/9/20

23. **Question:** Current CPT coding guidance states that CPT code 99454 cannot be reported when monitoring occurs for fewer than 16 days of a 30-day period. While it is possible that remote physiologic services (RPM) could be used to monitor a patient with COVID-19 for more than 16 days, many patients with COVID-19 may not need to be monitored for as many as 16 days. Can practitioners bill for RPM when a patient needs to be monitored for fewer than 16 days?
Answer: For the same reasons we established other policies supporting use of RPM services as part of the pandemic response, we are establishing a policy on an interim basis for the duration of the PHE for COVID-19 that monitoring for fewer days than 16 of 30 days, but no less than 2 days, can be reported as long as the other requirements for billing the code are met. However, in order to bill and receive reimbursement for RPM services with fewer than 16 days of monitoring, the receiving patient must have a confirmed or suspected case of COVID-19.
New: 6/19/20

24. **Question**: Are beneficiary-provided vital signs sufficient to satisfy that portion of the annual wellness visit (AWV) when conducted via telehealth?
Answer: If the beneficiary is at home and has access to the types of equipment they would need to self-report vital signs (e.g., weight, blood pressure), and if the visit meets all other requirements of the code, this scenario would satisfy the requirements for purposes of

billing the AWV code.

CMS maintains a list of services that are normally furnished in-person that may be furnished via Medicare telehealth during the PHE. This list is available here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
New: 5/27/2020

25. **Question**: What telephone-only service codes were finalized as telehealth services for the duration of the PHE?
Answer: For purposes of the PHE for the COVID-19 pandemic, Medicare has added several codes that describe telephone-only services to the list of Medicare telehealth services. These include CPT codes 99441–99443, which describe audio-only telephone evaluation and management (E/M) phone visits with practitioners who can independently bill for E/M services. While these codes are ordinarily limited to established patients, during the PHE, Medicare will make payment for them for both new and established patients. These services are noted on the list of telehealth services at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

Please report the POS that would have used had the service occurred in person for these telephone-only service codes and all other telehealth services during the PHE.

In addition, while not currently on the Medicare telehealth services list, during the PHE for COVID-19, CMS pays CPT codes 98966–98968, which describe audio-only telephone assessment and management visits for practitioners who cannot independently bill for E/M phone visits, for example certain therapists, social workers, and clinical psychologists.
New: 5/27/2020

26. **Question**: If the video connection is disconnected during an audio-video Medicare telehealth visit due to technological issues, can the visit still be billed as Medicare telehealth?
Answer: Practitioners should report the code that best describes the service. If the service was furnished primarily through an audio-only connection, practitioners should consider whether the telephone evaluation and management or assessment and management codes best describe the service, or whether the service is best described by one of the behavioral health and education codes for which we have waived the video requirement during the PHE for the COVID-19 pandemic. If the service was furnished primarily using audio-video technology, then the practitioner should bill the appropriate code from the Medicare telehealth list that describes the service. Note that CPT codes 99441–99443, which describe audio-only telephone E/M phone visits with practitioners who can

independently bill for E/M services, have been added to the Medicare telehealth list for the purposes of the PHE for the COVID-19 pandemic, and payment rates for these codes are set to be the same as the analogous in-person E/M visits.
New: 5/27/2020

27. **Question**: How should the CS modifier, which removes application of beneficiary cost-sharing (deductible and co-payment), be applied to telehealth services and/or E/M visits?
Answer: The CS modifier should be applied for certain evaluation and management services related to COVID-19 testing, whether they are furnished in person or via telehealth. These services are medical visits under the HCPCS evaluation and management categories described below when outpatient providers, physicians, or other providers and suppliers who bill Medicare for Part B services orders or administers a COVID-19 lab test, regardless of the HCPCS codes they use to report the test. Cost-sharing does not apply for COVID-19 testing-related services, which are medical visits that: are furnished between March 18, 2020, and the end of the PHE; result in an order for or administration of a COVID-19 test; are related to furnishing or administering such a test or to the evaluation of an individual for purposes of determining the need for such a test; and are in any of the following categories of HCPCS evaluation and management codes:
    - Office and other outpatient services
    - Hospital observation services
    - Emergency department services
    - Nursing facility services
    - Domiciliary, rest home, or custodial care services
    - Home services
    - Online digital evaluation and management services

    Cost-sharing does not apply to the above medical visit services for which payment is made to:
    - Hospital Outpatient Departments paid under the Outpatient Prospective Payment System
    - Physicians and other professionals under the Physician Fee Schedule
    - Critical Access Hospitals (CAHs)
    - Rural Health Clinics (RHCs)
    - Federally Qualified Health Centers (FQHCs)

    For services furnished on or after March 18, 2020, and through the end of the PHE, outpatient providers, physicians, and other providers and suppliers that bill Medicare for Part B services under these payment systems should use the CS modifier on applicable claim lines to identify the service as subject to the cost-sharing waiver for COVID-19 testing-related services and should NOT charge Medicare patients any co-insurance and/or

deductible amounts for those services.

Additionally, the CPT telehealth modifier, modifier 95, should be applied to claim lines that describe services furnished via telehealth. And the billing practitioner should report the POS code that reflects the place the service would have been furnished if furnished in-person.
Update: 7/24/2020

28. **Question**: Do Medicare telehealth services require CR ("catastrophe/disaster related") modifier and/or DR ("disaster related") condition code?
Answer: No, the CR and DR modifiers are not necessary for Medicare telehealth services.
New: 5/27/2020

29. **Question**: What codes can emergency physicians use if they want to perform telehealth services?
Answer: ED physicians can perform telehealth services from any location. CMS has temporarily added the ED E/M codes (CPT codes 99281–99285), the critical care codes (CPT codes 99291 and 99292), and the observation codes (CPT codes 99217–99220, 99224–99226, and 99234–99236) to the list of Medicare telehealth services for the duration of the COVID-19 PHE. When delivering emergency telehealth services, ED physicians should use the code that most accurately reflects that service and use the same place of service code that they would have used if that service was delivered in-person. The CPT telehealth modifier, modifier 95, should be applied to claim lines that describe services furnished via telehealth. For example, regardless of location, ED physicians who are delivering emergency services can use the ED E/M codes with place of service 23 (ED) and apply modifier 95.

When a practitioner furnishes services to a patient who is at the same location, such as when the practitioner and patient are in different areas of the same hospital, the services are not considered telehealth services. Instead, the services should be reported as in-person services.
New: 5/27/2020

30. **Question**: How should telehealth services be documented in the medical record (e.g., face-to-face time, preparation time)?
Answer: We expect the same level of documentation that would ordinarily be provided if the services furnished via telehealth were conducted in person.
New: 5/27/2020

31. **Question**: Can Physician Assistants (PAs) provide and bill for Interprofessional Telephone/Internet/Electronic Health Record Consultations (codes 99446–99449 and

99451)?
Answer: Yes, a PA can furnish these interprofessional consultation services, and the usual billing rules for PA services apply.
New: 5/27/2020

32. **Question**: How should practitioners bill for audio-only services that last longer than 30 minutes?
Answer: During the PHE for the COVID-19 pandemic, Medicare has added to the list of telehealth services CPT codes 99441–99443, which describe audio-only phone visits with practitioners who can independently bill for E/M services, and CPT codes 98966–98968, which describe audio-only phone visits with practitioners who cannot independently bill for E/M services (for example certain therapists, social workers, and clinical psychologists). CPT codes 99443 and 98968 describe 21–30 minutes of medical discussion, respectively for each practitioner type; but there are no CPT codes available to describe medical discussions lasting longer than 30 minutes.
New: 5/27/2020

33. **Question:** Is beneficiary consent required for virtual check-ins, e-visits, audio-video telehealth visits, and/or telephone-only E/M telehealth visits?
Answer: Beneficiary consent to receive virtual check-ins and e-visits is required although it may be obtained once annually and, during the PHE for the COVID-19 pandemic, consent may be obtained at the same time the service is furnished. Similar to services furnished in person, the patient's consent is not required to be noted on the medical record for telehealth services furnished using interactive audio-video technology. The audio-only phone visits also do not require the patient's consent to be noted in the medical record.
New: 5/27/2020

34. **Question**: Should practitioners use the same telehealth billing codes if the audio-video or audio-only appointment includes Teletype (TTY), relay services, accessible software, interpreter services support, or other means of effective communication?
Answer: Yes, if a practitioner receives TTY, relay services, accessible software, interpreter services support, or other means of effective communication, then they would use the same billing codes for when they don't need TTY, relay services, accessible software interpreter services, or other means of effective communication. Practitioners cannot charge patients more for a telehealth visits if the patient requires TTY relay services, accessible software, interpreter services or other means of effective communication.
New: 5/27/2020

35. **Question:** Are services designated on the telehealth list as non-covered by Medicare eligible for payment during the PHE?
Answer: No. Services that are currently non-covered remain so unless subsequent

rulemaking is undertaken to make them covered services. These services were added to the telehealth list for informational purposes only, to reflect stakeholder requests.
New: 5/27/2020

36. **Question:** What has changed for telephone E/M visits (CPT codes 99441–99443)?
Answer: On an interim basis during the PHE for the COVID-19 pandemic, Medicare payment for CPT codes 99441-99443 for claims with dates of service on or after March 1 is increased to align with the payment rates for the level 2–4 established patient office/outpatient E/M services (CPT codes 99212-99214). CMS has also added these services to the Medicare telehealth services list. These codes may be billed for both new and established patients during the PHE, and should be billed in accordance with the rules established for billing telehealth services during the PHE.
New: 6/19/20

37. **Question:** What time should be used to select the correct level of office/outpatient E/M visit when selecting the level based on time?
Answer: On an interim basis for the duration of the PHE for the COVID-19 pandemic, practitioners should use the typical time as specified in the CPT code descriptor for purposes of level selection when selecting based on time.
New: 6/19/20

38. **Question:** What is changing about the process by which CMS adds services to the Medicare telehealth list?
Answer: For the duration of the PHE for the COVID-19 pandemic, CMS will consider and make appropriate additions of services to the Medicare telehealth list on a rolling basis as services are identified by the public or through internal review. The current Medicare telehealth services list can be found at this website: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
New: 6/19/20

39. **Question:** What should practitioners consider while setting up agreements with vendors of telehealth and telecommunication technology to ensure that telehealth is accessible to all patients?
Answer: We remind stakeholders that access to telehealth and telecommunications technology must be inclusive, especially for those patients who may have disabilities where the use of technology and/or communication may be more challenging. Section 504 of the Rehabilitation Act and the Americans with Disabilities Act protect qualified individuals with disabilities from discrimination on the basis of disability in the provision of benefits and services. To provide these individuals with effective communications, covered entities must provide auxiliary aids and services when needed. We encourage providers to

discuss what aid or service is appropriate with the person with a disability making the request. For more information on best practices in serving deaf and hard of hearing individuals see https://www.nad.org/covid19-telehealth-access-for-providers/. Concerns related to potential discrimination issues under 504 should be referred to the Office of Civil Rights for further review.
New: 6/19/20

40. **Question:** How will recently enacted legislation allow CMS to utilize Medicare telehealth to address the declared COVID-19 public health emergency (PHE)?
Answer: The Coronavirus Preparedness and Response Supplemental Appropriations Act, as signed into law by President Trump on March 6, 2020, broadened a provision that allowed the Secretary of the Department of Health and Human Services to waive certain Medicare statutory and regulatory telehealth payment requirements. The Secretary exercised this waiver authority to lift limitations on the originating sites at which Medicare patients may be located to receive telehealth services during the PHE declared by the Secretary January 31, 2020. Exercising this waiver authority allowed beneficiaries in all areas of the country to receive telehealth services wherever they are located, including at their home. Using the further broadened waiver authority under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), CMS allows more types of healthcare practitioners to furnish and bill for Medicare telehealth services, and certain services can be furnished via telehealth using audio-only communications technology, during the PHE.
New: 6/19/20

41. **Question:** Are telehealth services limited to services for patients with COVID-19?
Answer: No. The CARES Act amendment broadens telehealth flexibility without regard to the diagnosis of the patient. This is a critical point given the importance of social distancing and other strategies recommended to reduce the risk of COVID-19 transmission, since the use of telehealth services can prevent vulnerable beneficiaries from entering a health care facility when their needs can be met remotely. For example, a beneficiary could use communications technology flexibility to have a visit with a doctor before receiving a prescription refill. However, Medicare telehealth services, like all Medicare services, must be reasonable and necessary under section 1862(a) of the Act in order to be covered.
New: 6/19/20

42. **Question:** Can physicians and other practitioners furnish Medicare telehealth services to beneficiaries in their homes?
Answer: Yes. The waiver temporarily eliminates the requirement that the originating site must be a physician's office or other specified type of healthcare facility located in a rural area, and allows Medicare to pay for telehealth services furnished to beneficiaries in their homes or any setting of care.

New: 6/19/20

43. **Question:** Which healthcare professionals can furnish and bill for diabetes self-management training (DSMT) services they furnish via telehealth?
Answer: During the COVID-19 Public Health Emergency (PHE), Centers for Medicare & Medicaid Services (CMS) announced a waiver that expands the types of healthcare professionals that can furnish telehealth services. Under this waiver, professionals that are eligible to bill Medicare Part B directly for DSMT services, i.e., accredited and certified DSMT programs that have been approved by a Medicare Administrative Contractor (MAC), may furnish and bill for DSMT services furnished via telehealth for the duration of the COVID-19 PHE. Further, under additional waiver authority in effect for the duration of the COVID-19 PHE, CMS has also designated DSMT services as educational services that may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology.
New: 7/28/20

44. **Question:** Can DSMT services provided by hospitals be billed as telehealth services?
Answer: Hospital outpatient departments may serve as originating sites and bill for an originating site facility fee when DSMT services are furnished to outpatients via telehealth by practitioners who may furnish and bill independently for DSMT services. However, if the DSMT service is being furnished by hospital staff as an outpatient hospital service, the section 1135 blanket waivers allow a hospital to provide DSMT services to a patient located at their home when the home serves as a relocated provider-based department or temporary expansion location of the hospital during the COVID-19 PHE. Hospitals should review requirements for providing hospital services in relocated provider-based departments including the patient's home and temporary expansion locations as appropriate.
New: 7/28/20

45. **Question:** Can Medicare pay for telehealth services furnished by physicians or practitioners who are physically located outside of the United States?
Answer: No. Section 1862(a)(4) of the Act and our corresponding regulation at 42 CFR § 411.9 prohibit Medicare payment for services that are not furnished within the United States. This payment exclusion remains in effect during a public health emergency and is not affected by telehealth flexibilities put in place for the COVID-19 PHE. While section 1834(m) of the Act permits payment for telehealth services that are furnished by a physician or practitioner at a distant site via a telecommunications system to a Medicare beneficiary at an originating site, a telehealth service is considered to be furnished at both the originating site and the distant site. Therefore, both the originating site and the distant site are subject to the statutory payment exclusion that prohibits Medicare payment for services that are not furnished within the United States.

New: 7/28/20

46. **Question:** Can the CPT codes 98966–98968 be used by registered dietitians or nutrition professionals (RDs/NPs) during the public health emergency based on CMS's decision to change these codes from "non-covered" to "covered" status?
Answer: Yes. Practitioners who are eligible to bill Medicare directly for their services, including RDs/NPs, may furnish and bill for the services described by CPT codes 98966-98968. Those CPT codes describe audio-only telephone assessment and management services furnished by practitioners who are eligible to bill Medicare directly for their services.

    We note that RDs/NPs are also eligible distant site practitioners, as defined in section 1842(b)(18)(C) of the Act, who are permitted to furnish and bill for telehealth services, including outside the circumstances of the PHE for COVID-19. All medical nutrition therapy (MNT) and diabetes self-management training (DSMT) services (with the exception of code G0271) are on the list of telehealth services. Please note that during the PHE for COVID-19, these telehealth services are among those that may be furnished via audio-only telecommunications technology (audio-video technology is not required).
    New: 10/20/20

47. **Question**: Should hospitals submit a separate 012x type of bill (TOB) for the telehealth originating site facility fee charges during an inpatient stay?
Answer: Yes, hospitals and critical access hospitals should bill their A/B/MAC for the originating site facility fee on a 12x TOB using the date of discharge as the line item date of service.
    New: 10/20/20

48. **Question:** Can audio-only phone E/M visits (CPT codes 99441–99443) be billed in the same month as chronic care management (CCM) services?
Answer: Yes. During the public health emergency (PHE), audio-only phone E/M visits (CPT codes 99441-99443) may be billed in the same month as chronic care management (CCM) services when reasonable and necessary and as long as time is not counted toward more than one code. We expect that in most cases the time counted toward CCM would be clinical staff minutes while the time counted for audio-only phone E/M services would represent a direct interaction between the patient and the billing professional. In general, for the duration of the PHE, CPT codes 99441-99443 can be used to report an office/outpatient E/M visit furnished by phone including during a month where chronic care management services are being furnished, and these codes can therefore be reported in the same time period as CCM services.
    New: 3/5/21

Q. Physician Services

1. **Question:** What does the IFC change for physician and practitioner billing?
   Answer: We are revising certain Medicare regulations to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare program during the public health emergency (PHE) resulting from the COVID-19 pandemic. To that end, the IFC makes temporary changes to certain policies regarding:

   - Supervision by a physician or non-physician practitioner
   - Payment for certain services furnished by teaching physicians and moonlighting residents
   - Telehealth and other communication technology-based services
   - Services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
   - Payment to laboratories for specimen collection

   New: 4/9/20

2. **Question:** What are the changes to supervision?
   Answer: In general, we are revising the definition of direct supervision to include, during the PHE, a virtual presence through the use of interactive telecommunications technology, for services paid under the Physician Fee Schedule as well as for hospital outpatient services. The revised definition of direct supervision also applies to pulmonary, cardiac, and intensive cardiac rehabilitation services during the PHE. Additionally, we changed the supervision requirements from direct supervision to general supervision, and to allow general supervision throughout hospital outpatient non-surgical extended duration therapeutic services. Most other therapeutic hospital outpatient services have been subject to general, rather than direct, supervision requirements since January 1, 2020. General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. General supervision may also include a virtual presence through the use of telecommunications technology but we would note that even in the absence of the PHE general supervision could be conducted virtually, such as by audio-only telephone or text messaging.
   New: 4/9/20

3. **Question:** When do the changes on supervision take effect and for how long?
   Answer: The changes to supervision rules are effective for services beginning March 1, 2020, and last for the duration of the COVID-19 Public Health Emergency.
   New: 4/9/20

4. **Question:** Are there any changes in how hospitals account for resident time at alternate locations?

Answer: Existing regulations have specific rules on when a hospital may count a resident for purposes of Medicare graduate medical education payments. Currently, if the resident is performing activities within the scope of his/her approved program in his/her own home, or a patient's home, the hospital may not claim the resident. We are changing the regulations so if the resident is at home or in a patient's home, but performing duties within the scope of the approved residency program and meets appropriate physician supervision requirements, a hospital that is paying that resident's salary and fringe benefits can claim that resident for IME and DGME purposes. This allows residents to perform their duties in alternate locations, including their home or a patient's home, so long as it meets appropriate physician supervision requirements.
New: 4/9/20

5. **Question:** Can residents furnish telehealth services?
   Answer: Through this interim final rule, for the duration of the PHE for the COVID-19 pandemic, we are allowing Medicare payment for services billed by teaching physicians when residents furnish telehealth services to beneficiaries under direct supervision of the teaching physician which is provided by interactive telecommunications technology. Medicare may also make payment for services billed by the teaching physician under the so-called primary care exception under our regulation at section 415.174 when a resident furnishes telehealth services to beneficiaries under the direct supervision of the teaching physician by interactive telecommunications technology.
   New: 4/9/20

6. **Question:** Does Medicare pay for a doctor or non-physician practitioner (NPP) to furnish care in a beneficiary's home?
   Answer: Medicare pays for evaluation and management (E/M) and other services (e.g., injections, venipunctures.) furnished in a beneficiary's home by a physician or NPP. Medicare pays for Medicare telehealth services, which include many services that are normally furnished in-person. Under the emergency declaration and waivers, these services may be provided to patients by physicians and certain non-physician practitioners regardless of the patient's location. Additionally, Medicare makes payment for a number of non-face-to-face services that can be used to assess and manage a beneficiary's conditions. These services include: care management, remote patient monitoring, and communication technology based services, e.g., remote evaluation of patient images/video and virtual check-ins. Importantly, Medicare will also pay physicians for care furnished in the patient's home by auxiliary personnel as long as those services are furnished incident to a physician's service and as long as the practitioner is providing appropriate supervision through audio/video communication when needed. In addition to personnel employed by the physician, this could potentially also include clinicians leased from other entities (e.g., a home health agency, home infusion provider, or ambulance provider). In these circumstances, payment for such services would be made to the billing practitioner who

would then make the appropriate payment to the contracted entity (for example, the home infusion provider).
Revised: 4/10/20

7. **Question:** Can the distant site practitioner furnish Medicare telehealth services from their home? Or do they have to be in a medical facility?
   Answer: There are no payment restrictions on distant site practitioners furnishing Medicare telehealth services from their home during the public health emergency. The practitioner should report the place of service (POS) code that would have been reported had the service been furnished in person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the PHE for the COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person.
   New: 4/10/20

8. **Question:** The ambulatory surgical center (ASC) in my community has recently converted to a hospital under unique provisions available during the PHE and my medical group has been contracted to provide care there. If clinicians from our medical group furnish covered professional services to Medicare beneficiaries at the ASC-turned-Hospital, can we bill Medicare for non-surgical services?
   Answer: Yes. Physicians and other practitioners who are permitted to bill under Medicare can bill Medicare for covered professional hospital services that are furnished to Medicare beneficiaries at an ASC that temporary enrolls as a hospital during the PHE. Practitioners would bill under the Medicare Physician Fee Schedule and follow existing billing rules for care furnished in a hospital. Practitioners should use the applicable place of service code depending on whether the ASC-turned-hospital is furnishing outpatient or inpatient care. Also, practitioners should add the modifier "CR" to professional claims for patients treated in temporary expansion sites during the Public Health Emergency.
   New: 4/10/20

9. **Question:** My medical group is contracted to provide care at a local hospital. The hospital has built a tent, transitioned a gymnasium, or converted another non-clinical location into a space to provide patient care. If clinicians from our medical group furnish covered professional services to Medicare beneficiaries at those new patient care locations, can we bill Medicare?
   Answer: Yes. Physicians and other practitioners who are permitted to bill under Medicare can bill Medicare for covered professional services that are furnished to Medicare beneficiaries at temporary expansion sites, including gymnasiums, or other non-clinical locations. Practitioners would bill under the Medicare Physician Fee Schedule and following existing billing rules for services furnished in the hospital. Practitioners should use the applicable place of service code depending on whether the temporary expansion site is

furnishing outpatient or inpatient care. Also, practitioners should add the modifier "CR" to professional claims for patients treated in temporary expansion site during the PHE.
New: 4/10/20

10. **Question:** The state or the Army Corps of Engineers, or other governmental entity established a new care location in our area by repurposing and retrofitting a convention center, gymnasium, or other site for patient care. My medical group has been asked to provide patient care in one of these locations. Can we bill Medicare for covered professional services furnished in these locations? If so are there reporting or billing rules that determine how this is done?
Answer: Yes. Physicians and other practitioners who are permitted to bill under Medicare can bill Medicare for covered professional services that are furnished to Medicare beneficiaries at temporary expansion sites, including those established by the state, the Army Corps of Engineers or other governmental entities. Practitioners would bill under the Medicare Physician Fee Schedule and following existing billing rules for services furnished in the hospital. Practitioners should use the applicable place of service code depending on whether the temporary expansion site is furnishing outpatient or inpatient care. Also, practitioners should add the modifier "CR" to professional claims for patients treated in temporary expansion site during the PHE.
New: 4/10/20

R. Scope of Practice

1. **Question:** Who is currently authorized under the Medicare regulations governing diagnostic tests to supervise the performance of diagnostic tests and what changes are being made for the public health emergency?
Answer: Medicare has different regulatory requirements for who may order a diagnostic test, furnish that test, and supervise the test. With regard to supervision, Medicare rules generally authorize only physicians (medical doctors and doctors of osteopathy) to provide the appropriate level of supervision assigned to a diagnostic test (42 CFR 410.32(b)(1)). However, throughout the duration of the COVID-19 public health emergency, we established an interim final policy that provides an exception to this basic rule at 42 CFR 410.32(b)(1) to also allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to provide the appropriate level of supervision assigned to a diagnostic test subject to applicable state law. In the CY 2021 Physician Fee Schedule final rule[2] issued December 2, 2020, we made this policy permanent, and included certified registered nurse anesthetists (CRNAs) among the non-physician practitioners who may supervise diagnostic tests. Under their statutory benefit category, NPs and CNSs continue to be required to furnish their professional services in collaboration with a physician; similarly, the relationship of PAs with physicians under our regulations would continue to apply.

[2] https://public-inspection.federalregister.gov/2020-26815.pdf

Updated: 12/11/20

2. **Question:** What changes is CMS making during the Public Health Emergency for Part B physical and occupational therapy services when it is necessary to carry out the services of a maintenance program – more commonly known as maintenance therapy – when needed to maintain, prevent or slow the deterioration of a patient's functional status?
   Answer: CMS has provided flexibility during the Public Health Emergency to allow physical and occupational therapists who established the maintenance program to delegate the performance of needed maintenance therapy services to therapy assistants, when clinically appropriate. This flexibility is applicable to all provider settings, including institutional providers and therapist private practices, where Part B outpatient therapy services are furnished.
   New: 6/19/20

3. **Question:** What requirements are being changed in regard to student documentation in the medical record?
   Answer: CMS has clarified that any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, for services they bill they may review and verify (sign and date), rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We are applying this broad flexibility to also include therapists. This aligns with policies adopted in the CY 2020 Physician Fee Schedule (PFS) final rule, where we finalized a policy to allow the physician, physician assistant (PA), or the advanced practice registered nurse (APRN) who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. This is not a change in the requirements for documentation in the medical record; rather, we are providing clarification on how that documentation can be provided.
   New: 6/19/20

4. **Question:** Is the policy for pharmacists performing services incident to the professional services of a physician or NPP a new policy or a clarification?
   Answer: This is not a new policy under Medicare. We clarified explicitly that pharmacists fall within the regulatory definition of auxiliary personnel under our incident to regulations. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.

New: 6/19/20

S. Additional Flexibility under the Teaching Physician Regulations

1. **Question:** Did CMS make changes related to the supervision of residents under the teaching physician regulations?
   Answer: Yes. In the March 31, 2020 COVID-19 IFC (85 FR 19230), we amended the regulation in 42 CFR 415.172 to state that for the duration of the PHE, the requirement for the presence of a teaching physician during the critical or key portion of the procedure can be met, at a minimum, through direct supervision by interactive telecommunications technology. In other words, the teaching physician must provide supervision either with physical presence or be present through interactive telecommunications technology during the critical key portion of the service.
   New: 6/19/20

2. **Question:** Can residents moonlight in the inpatient setting during the Public Health Emergency?
   Answer: Yes. In the March 31, 2020 COVID-19 IFC (85 FR 19230), we amended regulations at 42 CFR 415.208 to state that for the duration of the PHE, services of residents that are not related to their approved graduate medical education programs and are performed in the inpatient setting of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries in providers; the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and the services are not performed as part of the approved graduate medical education program.
   New: 6/19/20

3. **Question:** Under the "primary care exception" at 42 CFR 415.174, can the supervision of residents be performed through communications technology immediately following telehealth visits performed by residents?
   Answer: Yes. Under 42 CFR 415.174, which describes the so-called primary care exception, Medicare may make PFS payment for certain services of lower and mid-level complexity furnished by a resident without the presence of a teaching physician. The teaching physician reviews the care furnished by the resident during or immediately after each visit. In the May 8, 2020 COVID-19 IFC (85 FR 27550), for the duration of the PHE, we increased the flexibility to allow the teaching physician to supervise the resident during or immediately after each visit remotely through interactive communications technology. This means that if the teaching physician is in quarantine or otherwise not physically available, technology would enable the teaching physician to remotely supervise the resident.

New: 6/19/20

4. **Question:** Can a resident furnish telephone E/M services (CPT codes 99441–91443)?
   Answer: Yes. In the March 31st COVID-19 IFC (85 FR 19230), we stated that for the duration of the PHE, we are making separate payment for CPT codes 98966–98968 (for non-physician practitioners) and CPT codes 99441–99443 (for physicians). With respect to teaching physician supervision of residents, we introduced flexibility in 42 CFR 415.172 of the regulations to state that the teaching physician must provide supervision during the key portion of the service, either with physical presence or by being present through interactive telecommunications technology during the key portion of the service. This means that the resident can conduct a phone visit with a patient while being supervised virtually by the teaching physician. In the May 8, 2020 COVID-19 IFC (85 FR 27550), we stated that for the duration of the PHE, residents may also furnish CPT codes 99441–91443 under the primary care exception.
   New: 6/19/20

5. **Question:** What services are included in the primary care exception for the duration of the PHE?
   Answer: Under the regulation at 42 CFR 415.174, Medicare makes PFS payment in primary care settings for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician, referred to as the primary care exception. These services are listed in Chapter 12, Section 100.1.1.C of the Medicare Claims Processing Manual: Levels 1–3 of Office/Outpatient Evaluation and Management (E/M) Services for new patients (CPT codes 99201-99203) and established patients (CPT codes 99211–99213), Welcome to Medicare visit (HCPCS code G0402), and the Annual Wellness Visits (HCPCS codes G0438–G0439).

   In the March 31, 2020 COVID-19 IFC (85 FR 19230) for the duration of the PHE, we expanded the primary care exception to include all five levels of an office/outpatient E/M service (CPT codes 99201–99205 and CPT codes 99211–99215). Medicare may also make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services under the primary care exception.

   In the May 8, 2020 COVID-19 IFC, for the duration of the PHE, we also expanded the primary care exception to include the following services: Telephone E/M services (CPT codes 99441–99443), Transitional Care Management (CPT codes 99495-99496), and Communication Technology-Based Services (CPT codes 99421–99423 and 99452, and HCPCS codes G2010 and G2012). For office/outpatient E/M services furnished via telehealth, the E/M level selection can be based on Medical decision making (MDM) or time, with time defined as all of the time associated with the E/M on the day of the encounter. We also removed any requirements regarding documentation of history and/or physical exam in the medical

record.
New: 6/19/20

T. Home Infusion Services

1. **Question:** How can beneficiaries who are not leaving their home get infusion therapy? Can physician practices provide medically necessary drugs in the beneficiaries' home?
   Answer: Under existing policy eligible home infusion therapy suppliers (i.e., durable medical equipment (DME) suppliers enrolled in Medicare as pharmacies that provide external infusion pumps and supplies, who comply with Medicare's DME Supplier and Quality Standards, and maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered) can furnish medically necessary infusion therapy in the patient's home. See the following list of Frequently Asked Questions (FAQs) for more information on the home infusion therapy benefit, including a list of covered infusion drugs: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf

   Under existing policy, home health agencies also may administer medically necessary injected or infused drugs in the patient's home, if the patient or caregiver cannot self-administer, when part of the plan of care. CMS considers beneficiaries to be "confined to the home" (that is, "homebound") if it is medically contraindicated for the patient to leave the home. For example, a beneficiary could be considered "homebound" if: (1) a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

   Physicians (including those practicing in freestanding infusion centers) can furnish physicians' services, including medically necessary injected or infused drugs, in the patient's home. Through this interim final rule, physicians can also do this incident to their professional services, for example, under contract with auxiliary personnel, as defined in our regulation at §410.26(a)(1), to leverage additional staff and technology necessary to provide care outside their office setting under direct supervision using interactive audio-video technology. For example, physicians may enter into contractual arrangements with a home health agency (defined under section 1861(o) of the Act), a qualified infusion therapy supplier (defined under section 1861(iii)(3)(D) of the Act), or entities that furnish ambulance services in order to utilize their nurses or other clinical staff as auxiliary personnel under leased employment (§410.26(a)(5)). In such instances, Medicare payment for the physicians' direct and "incident-to" services would be made to the billing practitioner who would then make the appropriate payment to the contracted entity (for example, the HHA).

Payments would be made in accordance with the PFS and would not be considered a home health service under the Medicare home health benefit or a service under the home infusion therapy services benefit. Rather, the entity with which the physician contracts would seek payment for any services they provided from the billing practitioner and would not submit claims to Medicare for such services.
New: 4/9/20

2. **Question:** For physicians that are providing needed drugs in the patient's home incident to their professional services using auxiliary personnel, are there changes to physician supervision requirements?
   Answer: Through this interim final rule, CMS is altering supervision requirements for physicians and other practitioners. For the duration of the PHE for the COVID-19 pandemic, CMS is altering the definition of direct supervision at §410.32(b)(3)(ii), to provide that the necessary presence of the physician or other practitioner for direct supervision includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. We also note that this new flexibility would apply where the physician practice contracts with an entity for auxiliary personnel as defined in our regulation at §410.26(a)(1), including a home health agency, or a qualified home infusion therapy supplier, to provide incident-to services in the patient's home.
   New: 4/9/20

U. Medicare Shared Savings Program - Accountable Care Organizations (ACO)

1. **Question:** What happens if an Accountable Care Organization (ACO) or its participants do not report the Quality or Promoting Interoperability categories to the Merit-based Incentive Payment System (MIPS), and what happens if they do?
   Answer: For MIPS eligible clinicians (ECs) who participate in Shared Savings Program ACOs, if the ACO does not completely report quality and no ACO participant or MIPS EC in the ACO reports promoting interoperability (PI) due to extreme and uncontrollable circumstances, then the ACO will be eligible to have those two categories reweighted to zero percent, and the cost performance category will continue to be weighted at zero percent under the Alternative Payment Model (APM) scoring standard. Although MIPS ECs participating in Shared Savings Program ACOs will continue to receive full credit for Improvement Activities under the APM scoring standard, because it would be the only performance category that would be scored, the MIPS ECs participating in the ACO would instead receive a neutral payment adjustment under MIPS.

   In contrast, however, if the ACO completely reports quality and/or any ACO participant or MIPS EC in the ACO reports Promoting Interoperability, then all MIPS ECs that bill through the tax identification number (TIN) of an ACO participant in the ACO would receive a MIPS

score (based on ACO quality data and/or available Promoting Interoperability data, added to full credit for Improvement Activities, while the cost performance category would continue to be weighted at zero percent). The resultant MIPS payment adjustment could be upward, downward, or neutral.
Applicable Time Period: Performance Year 2019
Updated: 3/5/21

2. **Question:** MIPS ECs who have not submitted any MIPS data by April 30, 2020, will qualify for the automatic extreme and uncontrollable circumstances policy and will receive a neutral payment adjustment for the 2021 MIPS payment year, but for MIPS ECs who participate in Medicare Shared Savings Program (Shared Savings Program) ACOs, what happens if some but not all MIPS ECs or groups participating in the ACO report data for the PI performance category?
   Answer: If the ACO completely reports data for the Quality performance category and/or any ACO participant TIN or MIPS EC in the ACO reports data for the PI performance category, then all MIPS ECs that bill through the TIN of an ACO participant in the ACO would receive a MIPS score. Under the APM scoring standard, that score would be based on ACO quality data and/or available PI data, added to full credit for the Improvement Activities performance category, while the Cost performance category would continue to be weighted at zero percent. If some PI data is reported and quality data is not reported, the quality performance category would be re-weighted to zero percent in calculating the score. The resultant MIPS payment adjustment could be upward, downward, or neutral.

   With regard to the PI performance category, it is important to note that an ACO's PI score is the average of the scores for the MIPS ECs in the ACO. If a MIPS EC qualifies for a significant hardship or other type of exception for the PI performance category (as all MIPS ECs, including those who participate in APMs, do for performance year 2019 as a result of the current PHE), but chooses to submit data for the category as an individual or group, their data will be scored and will contribute to the ACO's PI score. If a MIPS EC does not report PI, they will be excluded from the calculation and will not negatively impact the ACO's overall PI performance category score.
   Applicable Time Period: Performance Year 2019
   Updated: 3/5/21

3. **Question:** Our organization is preparing the beneficiary notification for our Medicare FFS beneficiaries. In an effort to focus operational resources on the prevention and treatment of COVID-19 for our Medicare beneficiaries, can we delay proactive beneficiary notifications?
   Answer: CMS is aware that the COVID-19 PHE may impact an ACO's ability to furnish the standardized written notice to beneficiaries prior to or at the first primary care visit, as required by 42 CFR § 425.312(a)(2). CMS is sensitive to the challenges caused by the

pandemic and will consider the impact that these circumstances have on an ACO's ability to carry out the required beneficiary notifications in a timely manner. Accordingly, due to the PHE posed by COVID-19 and the urgent need for ACOs to focus on responding to the pandemic, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the deadline for furnishing the standardized written beneficiary notifications required under § 425.312(a) as long it is completed by the end of the applicable performance year.
Applicable Time Period: Performance Years 2020 and 2021
Updated: 3/5/21

4. **Question:** Our organization has experienced a significant reduction in office primary care visits due to the COVID-19 PHE. We would like to know how to provide the standardized written beneficiary notification in instances of e-visit and telehealth services?
Answer: Under 42 CFR § 425.312(a)(2), ACOs are permitted to distribute the annual standardized written notice to beneficiaries in a form and manner specified by CMS. CMS has stated in the Medicare Shared Savings Program Accountable Care Organizations Marketing and Outreach Materials Guidance that the standardized written notifications may be provided through electronic transmission (such as email or secure portal) or mail. These methods can be used in conjunction with e-Visits and Telehealth technology. CMS is sensitive to the challenges caused by the pandemic and will consider the impact that these circumstances have on an ACO's ability to carry out the required beneficiary notifications in a timely manner. Accordingly, due to the PHE posed by COVID-19 and the urgent need for ACOs to focus on responding to the pandemic, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the deadline for furnishing the standardized written beneficiary notifications required under § 425.312(a) as long it is completed by the end of the applicable performance year.
Applicable Time Period: Performance Years 2020 and 2021
Updated: 3/5/21

5. **Question:** What emergency preparedness and response resources are available for ACOs?
Answer: HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) Technical Resources, Assistance Center, and Information Exchange (TRACIE) has developed several emergency preparedness and response resources for healthcare facilities and emergency medical professionals, including a technical assistance (TA) document specifically addressing Engagement of ACOs in Medical Surge Activities.
New: 5/1/20

6. **Question**: If an ACO terminated its Shared Savings Program agreement effective August 31, 2020, and if the ACO were to incur shared losses for performance year 2020, for how many months would the ACO owe shared losses if the Extreme and Uncontrollable policy was triggered?

Answer: The Secretary's declaration of the COVID-19 Public Health Emergency (PHE) in January 2020 triggered the Medicare Shared Savings Program's Extreme and Uncontrollable Circumstances Policy. The extreme and uncontrollable circumstances of the COVID-19 PHE began in January 2020, and will apply nationwide for the duration of the PHE for the COVID-19 pandemic. Shared losses for performance year 2021 will be mitigated for all ACOs participating in a performance-based risk track, including: Track 2, the ENHANCED track (previously Track 3), the BASIC track, levels C through E, and the Track 1+ Model, based on the length of the PHE. For ACOs responsible for pro-rated shared losses under Medicare Shared Savings Program policies governing the payment consequences of early termination, and that experience an extreme and uncontrollable event during the calendar year in which their termination becomes effective: we will calculate the ACO's shared losses amount based on the 12 month calendar year, adjusting the shared losses amount to reflect the number of months and the percentage of the ACO's assigned beneficiary population affected by extreme and uncontrollable circumstances, before we calculate the pro-rated amount of shared losses for the portion of the year the ACO participated in the Shared Savings Program before termination. For example, if the COVID-19 PHE is in effect for 7 months of performance year 2021 (January through July) any shared losses an ACO incurs for the performance year will be reduced by at least 58.33% (for 7 of the 12 months). Then, if an ACO terminates on August 31st, the ACO would owe 66.66% (for 8 of the 12 months) of any remaining shared losses for the performance year after adjusting for the extreme and uncontrollable circumstance (see 42 CFR § 425.221(b)(2)). If the PHE covers the full year (January through December) any shared losses an ACO incurs for the performance year would be reduced completely, and the ACO would not owe any shared losses.
Applicable Time Period: Performance Year 2021 (refer to Question 17 for additional information).
Updated: 3/5/21

7. **Question:** Under the Medicare Shared Savings Program, SNFs approved to use a SNF 3-day rule waiver must normally have and maintain an overall rating of 3 stars or higher on the CMS 5-star Quality Rating System. Has CMS waived the Shared Savings Program star-rating requirement as well?
Answer: The Shared Savings Program has not waived the star-rating requirement under 42 CFR § 425.612(a)(1)(iii)(A). SNF affiliates of ACOs with an approved SNF 3-Day Rule Waiver must comply with the requirement to have and maintain an overall rating of 3 or higher if they are eligible to be included in the CMS 5-star Quality Rating System.
Applicable Time Period: Performance Year 2020 and 2021
Updated: 3/5/21

8. **Question:** When will the 2020 Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs final list of survey vendors be available and when do we authorize a

vendor to administer the survey on our behalf?
Answer: Due to the impact of the COVID-19 PHE for performance year 2020, CMS waived the CAHPS for ACOs reporting requirement and will assign all ACOs automatic credit for the CAHPS for ACOs survey measures.
Applicable Time Period: Performance Year 2020
Updated: 3/5/21

9. **Question:** Will CMS be conducting the Quality Measures Validation (QMV) Audit for the 2020 performance year for the Medicare Shared Savings Program ACOs?
Answer: CMS is continuing to evaluate the impact the COVID-19 PHE had on Shared Savings Program ACOs' quality reporting for the 2020 performance year in order to determine an approach for the QMV audit. We will review the data reported by ACOs via the CMS Web Interface to determine if any data anomalies would require us to look at the data more closely via an audit, consistent with our current process. After completing this review, CMS may opt against conducting a QMV audit for the 2020 performance year. However, as provided in 42 CFR § 425.500(e), we retain the right to ask for additional information from ACOs or to conduct a targeted audit if egregious data anomalies are found.
Applicable Time Period: Performance Year 2020
New: 3/5/21

10. **Question:** Can ACOs apply to participate in the Medicare Shared Savings Program for an agreement start date of January 1, 2021?
Answer: No, on May 8, 2020 CMS announced that it was forgoing the annual application cycle for a January 1, 2021 start date due to the COVID-19 public health emergency (See 85 FR 27574). ACOs with an agreement ending December 31, 2020, were eligible to elect to extend their current agreement for a fourth performance year, ending December 31, 2021. No ACO will have an agreement start date of January 1, 2021.
Applicable Time Period: Performance Year 2021
Updated: 3/5/21

11. **Question:** Is CMS offering Medicare Shared Savings Program ACOs with an agreement end date of December 31, 2020, the opportunity to extend their current agreement for one performance year?
Answer: Yes, CMS is providing a voluntary 12-month extension for existing Medicare Shared Savings Program ACOs whose participation agreements expire on December 31, 2020. We believe it is necessary to offer this extension, so that ACOs whose first or second agreement periods expire December 31, 2020, can continue their participation in the program without interruption and without the burden of applying to renew their participation agreement during summer and fall of 2020.
Applicable Time Period: Performance Year 2021

Updated: 3/5/21

12. **Question:** How does an ACO whose Medicare Shared Saving Program participation agreement is set to expire on December 31, 2020, voluntarily elect to extend its current agreement period in the Medicare Shared Savings Program for an additional performance year in 2021?
Answer: All ACOs with an agreement period ending on December 31, 2020, that wish to extend their agreement for an additional performance year will need to log into the ACO-Management System (ACO-MS) to make their voluntary election beginning June 18, 2020. CMS will provide a more detailed schedule and instructions for all ACOs through the ACOMS Knowledge Library.

    ACOs that **elect to extend** their agreement period will need to take the following steps:
    • Certify that they have notified their ACO participants and, if applicable, SNF affiliates of their continuation in the program in 2021; and
    • If necessary, update their agreements with ACO participants and, if applicable, SNF affiliates to reflect participation for performance year 2021 and certify that any such updates have been made. ACOs do not need to submit updated ACO Participant or SNF Affiliate Participant agreements reflecting the extension to CMS for review, unless CMS requests to review these documents.

    We anticipate the final date by which an ACO must complete its voluntary election will be September 22, 2020, at 12 p.m. ET. Please note, all dates are subject to change. ACOs currently participating in the Shared Savings Program should visit the ACO-MS Knowledge Library for additional information.

    ACOs that **do NOT elect to extend** their agreement period and do not voluntarily terminate early will end participation in the Shared Savings Program on December 31, 2020, and must complete closeout actions in the form and manner and by the deadline specified by CMS. These ACOs should monitor email for additional information regarding closeout procedures.
    Applicable Time Period: Performance Year 2020 to take effect during Performance Year 2021
    Updated: 3/5/21

13. **Question:** How does an ACO that is currently participating in the BASIC track's glide path voluntarily elect to maintain its participation level for performance year 2021?
Answer: All ACOs currently participating in the BASIC track's glide path may elect to maintain or "freeze" their current participation level for performance year 2021. For example, an ACO participating in BASIC track Level B for performance year 2020 may elect to maintain its participation level for performance year 2021. ACOs wishing to "freeze"

their BASIC track glide path participation level will need to log into the ACO-Management System (ACO-MS) to make their voluntary election beginning June 18, 2020. CMS will provide a more detailed schedule and instructions for all ACOs through the ACO-MS Knowledge Library. Note, an ACO that elects this advancement deferral option will be automatically advanced for PY 2022 to the level of the BASIC track's glide path in which it would have participated if it had advanced automatically to the next level for PY 2021. For example, if an ACO participating in the BASIC track Level B in PY 2020 elects to maintain its current level of participation for PY 2021, it will participate under Level B for PY 2021 then will automatically advance to Level D for PY 2022 (unless the ACO voluntarily chooses to advance to Level E for PY 2022).

ACOs that do not elect to maintain their current participation level for PY 2021 by the date specified by CMS, will automatically advance to the next level of the BASIC track's glide path, or to a higher level if the ACO voluntarily elects to advance more quickly, effective January 1, 2021.
Applicable Time Period: Performance Year 2020 to take effect during Performance Year 2021
Updated: 3/5/21

14. **Question:** If I am an ACO currently participating in the Shared Savings Program, what participation option changes can I make for performance year 2021?
Answer: Currently participating ACOs that meet eligibility criteria may apply for a SNF 3-day rule waiver or to establish a beneficiary incentive program. Currently participating ACOs may modify their ACO participant list and/or SNF affiliate list for performance year 2021. Eligible ACOs may also elect to change their selection of beneficiary assignment methodology or advance more quickly along the BASIC track's glide path. Additionally, ACOs participating in the BASIC track's glide path may elect to maintain their performance year 2020 participation level for performance year 2021. ACOs will be able to make their voluntary elections, apply for a SNF 3-day rule waiver or to establish a beneficiary incentive program, or submit change requests in ACO-MS beginning June 18, 2020.

We updated the following documents to accompany the participation options change request review schedule:
- Medicare Shared Savings Program Skilled Nursing Facility 3-Day Rule Waiver Application
- Medicare Shared Savings Program Beneficiary Incentive Program Application
- Shared Savings Program ACO Participation Options
- ACO Participant List and Participant Agreement Guidance
- Skilled Nursing Facility 3-Day Rule Waiver Guidance
- Beneficiary Incentive Program Guidance
- Repayment Mechanism Arrangements Guidance
- ACO Banking Form Guidance

• Shared Savings Program Participation Options Table
• Shared Savings Program Participation Options Tip Sheet ACOs can access the updated documents on the Shared Savings Program website and in the ACO-MS Knowledge Library.
Applicable Time Period: Performance Year 2020 to take effect during Performance Year 2021
Updated: 3/5/21

15. **Question:** When is the next opportunity to apply to participate in the Shared Savings Program?
Answer: The next available Shared Savings Program application cycle will be for a January 1, 2022 agreement start date. The application cycle will occur in calendar year 2021. We encourage you to monitor the Shared Savings Program website for updated information.
New: 6/19/20

16. **Question:** For the Medicare Shared Savings Program, what is the schedule for ACOs to submit change requests to modify their participation options, ACO participant list, and/or SNF affiliate lists for performance year 2021?
Answer:

ACTION	ACO RESPONSE PERIOD
INITIAL CHANGE REQUEST SUBMISSION	6/19 – 7/20/20 at 12:00 p.m. (noon) Eastern Time (ET)
RFI-1 RESPONSE PERIOD	8/11 – 8/24/20 at 12:00 p.m. (noon) ET
RFI-2 RESPONSE PERIOD	9/16 – 9/22/20 at 12:00 p.m. (noon) ET
FINAL DISPOSITION	10/20/20 at 12:00 p.m. (noon) ET
ANNUAL CERTIFICATION	10/27 – 11/9/20 at 12:00 p.m. (noon) ET

Dates are subject to change and any updates will be made available through the ACO Spotlight newsletter.

Eligible ACOs can take the following actions during the initial change request submission period and the first and second Request for Information (RFI-1 and RFI-2) response periods:
• Voluntary election to extend agreement period for an optional fourth performance year for ACOs whose participation agreements are scheduled to end December 31, 2020.
• Voluntary election to maintain current level under the BASIC track for performance year 2021 or transition to a higher level of risk and reward within the BASIC track's glide path. To participate under a performance-based risk level, the ACO must establish an adequate repayment mechanism and select a minimum savings rate (MSR)/minimum loss rate (MLR).
• Apply for a Skilled Nursing Facility (SNF) 3-Day Rule Waiver and/or to establish a Beneficiary Incentive Program (BIP).
• Add ACO participant and/or SNF affiliate change requests.
• Change selection of beneficiary assignment methodology. We anticipate the final date by

which an ACO must complete its voluntary election(s) is September 22, 2020, at 12 p.m. ET. Please note, all dates are subject to change. ACOs currently participating in the Shared Savings Program should visit the ACO-MS Knowledge Library for additional information.
Applicable Time Period: Performance Year 2020 to take effect during Performance Year 2021
Updated: 3/5/21

17. **Question:** How is CMS applying the Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy to shared losses?
Answer: The Secretary's declaration of the COVID-19 PHE in January 2020 triggered the Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy. The extreme and uncontrollable circumstances of the COVID-19 pandemic will apply starting in January 2020 and extend for the duration of the PHE as specified in 42 CFR § 400.200. Shared losses will be mitigated for all ACOs participating in a performance-based risk track (or payment model within a track): Track 2, the ENHANCED track, Levels C, D and E of the BASIC track, and the Track 1+ Model. Since the PHE for COVID-19 was still in effect in December 2020, all shared losses for performance year 2020 will be mitigated. The Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy will continue to apply for the duration of the PHE. The PHE for COVID-19 continues to be in effect in 2021. If the PHE covers 3 months of 2021 (January through March) any shared losses an ACO incurs for performance year 2021 would be reduced by one-fourth; if the PHE covers 6 months of 2021 (January through June) any shared losses an ACO incurs for performance year 2021 would be reduced by one-half; if the PHE covers 9 months of 2021 (January through September) any shared losses an ACO incurs for performance year 2021 would be reduced by three-fourths; and if the PHE covers the full year (January through December 2021) any shared losses an ACO incurs for performance year 2021 would be reduced completely, and the ACO would not owe any shared losses.
Applicable Time Period: Performance years 2020 and 2021
Updated: 3/5/21

18. **Question.** Is CMS expanding the list of primary care services used for beneficiary assignment in the Medicare Shared Savings Program?
Answer. Yes, in recognition of the increased use of telehealth and other technology-based services, we expanded the list of primary care services used in determining beneficiary assignment when the assignment window (as defined at §425.20) for a benchmark or performance year includes any months during the PHE for COVID-19 defined in 42 CFR 400.200, to include remote evaluation of patient video/images, virtual check-ins, online digital evaluation and management services (e-visits), and telephone evaluation and management services. We will apply the additional primary care service codes listed in the chart below to all months of the assignment window (as defined in §425.20), when the

assignment window includes any month(s) during the PHE for COVID-19 defined in §400.200.

Category	List of codes (CPT or HCPCS)
Remote Evaluation of Patient Video/Images and Virtual Check-In	G2010, G2012
E-Visits	99421, 99422, and 99423
Telephone Evaluation and Management	99441, 99442, and 99443

We also clarify that those HCPCS and CPT codes included in the List of Telehealth Services that are also included in the Shared Savings Program definition of primary care services for purposes of assignment in § 425.400(c) are used for assignment regardless of whether they are furnished in person or via telehealth, provided they are billable and payable under Medicare FFS payment policies and a relevant place of service exclusion is not included for the codes in our assignment methodology. The codes for E-visits and for Remote Evaluation of Patient Video/Images and Virtual check ins have been permanently added to the definition of primary care services in § 425.400(c) and are no longer limited to the PHE starting in PY2021.
Applicable Time Period: Performance years 2020 and 2021
Updated: 3/5/21

19. **Question.** How is CMS mitigating the impact of increased COVID-19 related expenditures in Medicare Shared Savings Program calculations?
Answer: In accordance with § 425.611, we are excluding from Shared Savings Program financial calculations all Parts A and B fee-for-service (FFS) payment amounts for an episode of care triggered by an inpatient service for treatment of COVID-19. CMS will identify an episode of care, based on either: (1) discharges for inpatient services eligible for the 20 percent DRG adjustment under section 1886(d)(4)(C) of the Social Security Act, or (2) discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the PHE as defined in 42 CFR § 400.200. We will define the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date.

CMS will adjust the following Shared Savings Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19:

• Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes including the following: establishing, adjusting, updating, and

resetting the ACO's historical benchmark, and determining performance year expenditures.
• Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including for calculating average county FFS expenditures, truncating expenditures, capping the regional adjustment to the ACO's historical benchmark, and trending forward and updating the ACO's benchmark
• Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in 42 CFR § 425.605(d).
• Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under 42 CFR § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).
• Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to 42 CFR § 425.204(f)(4).
Applicable Time Period: Performance years 2020 and 2021
Updated: 3/5/21

20. **Question:** Will advance / accelerated payments and payments made through the CARES Act Provider Relief Fund be included in Medicare Shared Savings Program ACO's financial reconciliation calculation?
Answer: There are certain payments related to the COVID-19 PHE that fall outside of Medicare FFS Parts A and B claims, and by virtue of this fact, these payments will not be utilized under the Shared Savings Program methodology for determining beneficiary expenditures. For example, we would not account for payment or recoupment of accelerated or advance payments, which are merely advances and repayments of loans. This is because the underlying Parts A and B claims used in Shared Savings Program expenditure calculations would continue to reflect the amount the providers/suppliers are eligible to be paid, although that payment may be subject to offset for repayment of accelerated or advance payments. Further, Shared Savings Program expenditure calculations would also not account for grant payments made to hospitals and other healthcare providers through the CARES Act Provider Relief Fund, which occur outside of Parts A and B claims. We will continue to capture Medicare FFS Parts A and B payments to providers / suppliers receiving these funds in Shared Savings Program calculations.

For additional information, see CMS, "Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID-19 Emergency," available at https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf and the HHS website, CARES Act Provider Relief Fund, at

https://www.hhs.gov/provider-relief/index.html.
Applicable Time Period: Performance Years 2020 and 2021
Updated: 3/5/21

21. **Question:** Will diagnoses from telehealth visits be used in the CMS-HCC risk scores used in program calculations for ACOs? Are ACOs included in the 'other organizations' that may submit diagnoses codes that are referenced in the 4/10/2020 HPMS memo that addressed the applicability of diagnoses from telehealth visits for purpose of risk adjustment?
Answer: CMS calculates risk scores for all Medicare beneficiaries, and uses the final CMS-HCC risk scores calculated for FFS beneficiaries in ACO program calculations; the Medicare Shared Savings Program and existing CMMI ACO models do not calculate separate CMS-HCC risk scores for these ACO initiatives. Final CMS-HCC risk scores will include telehealth visits when those visits meet all criteria for risk adjustment eligibility, which include being from an allowable inpatient, outpatient, or professional service. Diagnoses resulting from telehealth services can meet the risk adjustment face-to-face requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication.

While Medicare Advantage organizations submit diagnoses for their enrollees, CMS calculates the risk scores of FFS beneficiaries, including those assigned to ACOs, with those diagnoses that are submitted on claims by FFS providers, and that meet risk adjustment criteria. CMS uses the information on these FFS claims to determine whether diagnoses are risk adjustment eligible, including those from telehealth visits. In other words, when diagnoses from applicable telehealth visits meet the risk adjustment criteria, they will be used in calculating risk scores for FFS beneficiaries.

The 4/10/20 HPMS memo was referring to plans that submit diagnoses on behalf of their enrollees, and that submit data to the Risk Adjustment Processing System (RAPS) or Encounter Data System (EDS) for purposes of calculating risk scores. Because beneficiaries participating in ACOs are FFS beneficiaries, and CMS uses diagnoses from FFS claims to calculate their risk scores, ACOs are not considered 'other organizations' and do not submit data to RAPS or EDS for purposes of calculating risk scores.

For information on how the CMS-HCC risk scores are calculated, please refer to the Medicare Managed Care Manual, Chapter 7, Risk Adjustment (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf). If additional information is needed, please email RiskAdjustmentPolicy@cms.hhs.gov.

Applicable Time Period: Performance Years 2020 and 2021
Updated: 7/2/21 (changes to link and contact email in last paragraph only)

22. **Question**: How will Medicare Shared Savings Program calculations adjust for the suspension of the sequestration adjustment?
Answer: As announced in the MLN Connects, section 3709 of the CARES Act temporarily suspended the two percent payment adjustment currently applied to all Medicare FFS payments due to sequestration. The suspension is effective for claims with dates of service from May 1 through December 31, 2020 (refer to the April 10, 2020 MLN Connects Special Edition, available at https://www.cms.gov/files/document/2020-04-10-mlnc-se.pdf). The Consolidated Appropriations Act, 2021, signed into law on December 27, 2020, extends the suspension period to March 31, 2021 (refer to the December 28, 2020 MLN Connects Special Edition, available at https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-12-28-mlnc-se). Under current Medicare Shared Savings Program procedures, CMS adjusts shared savings payment amounts for sequestration by reducing them by two percent, as required by the Budget Control Act of 2011. This two percent reduction is applied after CMS applies the final shared savings rate to the ACO's savings and prior to applying the performance payment limit. For the duration of the suspension of the sequestration reduction, CMS will not apply the two percent reduction to ACO shared savings payments. This included shared savings payments for performance years (or a performance period) in 2019, which were paid during Fall 2020, within the suspension period.
Applicable Time Period: Performance Year 2019
Updated: 3/5/21

23. **Question**: Will Medicare FFS claims for items and services furnished during an episode of care for treatment of COVID-19 be used for purposes of assigning beneficiaries to a Medicare Shared Savings Program ACO even though payment amounts for these episodes are being excluded from certain program calculations?
Answer: Yes. Any primary care services included in the Medicare Shared Savings Program assignment methodology, described in 42 CFR part 425, subpart E, provided during an episode of care for treatment of COVID-19 (identified according to § 425.611) will be used for purposes of beneficiary assignment to the Medicare Shared Savings Program. Part B services provided during an inpatient stay that do not meet the definition of primary care services will not be used to assign beneficiaries to ACOs. While applicable payment amounts are used for purposes of determining the plurality of allowed charges for primary care services for purposes of beneficiary assignment, CMS will exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19, for purposes of determining performance year expenditures and establishing, adjusting, updating, and resetting the ACO's historical benchmark, among other program calculations as provided in § 425.611.
Applicable Time Period: Performance years 2020 and 2021
Updated: 3/5/21

24. **Question**: If ACO professionals only provide services to hospitalized beneficiaries either in inpatient facilities or temporary hospital expansion sites allowed under the new waivers, would these beneficiaries potentially get assigned to our Medicare Shared Savings Program ACO?
Answer: No. Inpatient hospital evaluation and management CPT codes (ranging from 99221 to 99239) are not used in beneficiary assignment in the Medicare Shared Savings Program. For example, if a family practitioner delivers a service with CPT code 99221, for new or established patient initial hospital inpatient care services, to a beneficiary admitted to an inpatient hospital, this service would not be included in determining plurality of primary care services for this beneficiary.
Applicable Time Period: Performance Year 2020 and subsequent years
Updated: 3/5/21

25. **Question**: If ACO professionals only provide services to beneficiaries in a Skilled Nursing Facility, would these beneficiaries potentially get assigned to a Medicare Shared Savings Program ACO?
Answer: No. Consistent with our current assignment methodology, CMS will exclude allowed charges for professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a Skilled Nursing Facility claim in our claims files with dates of service that overlap with the date of service for the professional service.
Applicable Time Period: Performance Year 2020 and subsequent years
Updated: 3/5/21

26. **Question:** Some ACOs have expressed concern about the impact of COVID-19 on prospective assignment for performance year (PY) 2021. What is CMS doing to address these concerns?
Answer: We are monitoring the potential impact of the COVID-19 pandemic on ACO assignment. It is important to note that ACOs in agreement periods beginning on July 1, 2019, and in subsequent years have the option to change their selection of beneficiary assignment methodology for PY 2022. ACOs concerned about the impact of the COVID-19 pandemic on prospective assignment may wish to elect preliminary prospective assignment with retrospective reconciliation for PY 2022. This option would be available to July 1, 2019 starters and January 1, 2020 starters for PY 2022, and ACOs entering a new agreement period beginning on January 1, 2022. New, re-entering ACOs, and renewing ACOs will have the opportunity to make their beneficiary assignment methodology selection during the application cycle for a January 1, 2022 start date. ACOs within an existing agreement period will have an opportunity to elect to change their beneficiary assignment methodology selection during the change request review cycle before the start of performance year 2022.
Applicable Time Period: Performance year 2021 to take effect during Performance Year

2022
Updated: 3/5/21

27. **Question**: When will the changes announced in the May 8, 2020 Interim Final Rule with Comment (IFC) be included in ACOs' quarterly program reports?
Answer: The May 8, 2020 IFC includes updates to the primary care services codes used in beneficiary assignment to add the codes for certain evaluation and management services provided remotely or via telehealth and also provides for the removal of all Parts A and B fee-for-service payment amounts for an episode of care triggered by an inpatient service for treatment of COVID-19 from program expenditure calculations. Due to the timing of their finalization, these policy changes are not reflected in the Performance Year (PY) 2020 Q1 reports. CMS anticipates that the updates to the assignment methodology to include remote evaluation of patient video/images, virtual check-ins, online digital evaluation and management services (e-visits), and telephone evaluation and management services will be reflected in preliminary prospective assignment beginning with PY 2020 Q2 reports provided in August. CMS also anticipates making expenditure and utilization data related to the removal of episodes of care for treatment of COVID-19 available to ACOs beginning with the PY 2020 Q2 reports in August. More information on the content and timing of these reports will be forthcoming.
Applicable Time Period: Performance Years 2020 and 2021
Updated: 3/5/21

28. **Question:** What claim types and facility types is CMS using to identify an inpatient service for treatment of COVID-19 to identify episodes of care for use in adjusting Shared Savings Program calculations?
Answer: To identify inpatient services that trigger an episode of care for treatment of COVID-19, we will use a combination of claim type, CMS certification number (CCN), and discharge with B97.29 or U07.1 diagnosis appearing on the claim. Specifically, we will use claim type 60 (inpatient claim) in combination with the following facility types as identified by the last four digits of the CCN or by the character in the third position of the CCN: Short-Term (General and Specialty) Hospitals (0001-0879); Hospitals that participated in an Office of Research and Development Demonstration Project (0880-0899); Critical Access Hospitals (CAHs) (1300-1399); Long Term Care Hospitals (LTCH) (2000-2299); Inpatient Rehabilitation Facilities (3025-3099), Children's Hospitals (3300-3399), Rehabilitation Units (T in third position); and CAH Rehabilitation Units (R in third position).

This approach will capture claims for inpatient services, which include services provided at a hospital expansion site, and "under arrangements" with other providers, or in excluded distinct part units repurposed for acute care services (such as a psychiatric unit), and services for swing-beds used for acute inpatient care.
Applicable Time Period: Performance years 2020 and 2021

Updated: 3/5/21

29. **Question:** When excluding from Shared Savings Program calculations Parts A and B FFS payment amounts for an episode of care for treatment of COVID-19, will COVID-19 admissions/stays in a Skilled Nursing Facility (SNF) trigger these episodes of care?
Answer: An episode of care is triggered by an inpatient service for treatment of COVID-19 (42 CFR § 425.611(b)). Under flexibilities in response to the COVID-19 pandemic, a SNF (for example) can work with hospitals under arrangements to be able to provide inpatient acute care to Medicare beneficiaries and these admissions would trigger an excluded COVID-19 episode of care. However, if the beneficiary's SNF admission is for post-acute services, this alone would not trigger an episode of care for treatment of COVID-19. It is important to note that if post-acute care, such as SNF care, follows the beneficiary's discharge from a facility or unit where they were receiving inpatient services for treatment of COVID-19, payment amounts for post-acute care in the month of and the month following the discharge date (along with all other Parts A and B services) will also be excluded.
Applicable Time Period: Performance years 2020 and 2021
Updated: 3/5/21

30. **Question:** Will the episode span the beginning of the month in which the admission date occurs through the end of the month following the month in which the discharge date occurs?
Answer: Yes, we explained in preamble to the May 8,' 2020 Interim Final Rule with Comment Period that the length of the episode of care is in units of months (85 FR 27580). We define the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date. This approach to measuring the length of the episode of care in units of months aligns with the Shared Savings Program's existing methodology for calculating benchmark year and performance year expenditures.

    For example: the beneficiary is admitted March 15 and discharged April 17; the episode length is March 1–May 31 and all Parts A and B FFS payment amounts with dates of service during this episode of care would be excluded from Shared Savings Program financial calculations, including the determination of performance year and benchmark year expenditures.
    Applicable Time Period: Performance years 2020 and 2021
    Updated: 3/5/21

31. **Question:** For a claim to be used to identify an episode of care for treatment of COVID-19 according to 42 CFR § 425.611, do International Classification of Diseases, Tenth Revision,

Clinical Modification (ICD-10-CM) codes B97.29 "Other coronavirus as the cause of diseases classified elsewhere" (for discharges occurring on or after January 27, 2020, and on or before March 31, 2020) or U07.1 "COVID-19" (for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE period) need to be the principal diagnosis on the claim?
Answer: We will identify claims for treatment of COVID-19, for use in identifying episodes of care, when the diagnosis code B97.29 or U07.1 is present in any diagnosis code field, based on established coding guidelines. For additional information, please refer to guidelines for providers for coding encounters related to COVID-19 (such as https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf), and CMS claims processing instructions (such as https://www.cms.gov/files/document/mm11764.pdf).
Applicable Time Period: Performance years 2020 and 2021
Updated: 3/5/21

32. **Question:** Are current procedural terminology (CPT) codes for administration of health risk assessment (96160 and 96161), outpatient visit for the evaluation and management for new (99201–99205) and established patients (99211–99215), transitional care management services (99495 and 99496), and advanced care planning (99497 and 99498) included in the definition of primary care services in 42 CFR § 425.400 and used for purposes of Medicare fee-for-service beneficiary assignment in the Medicare Shared Savings Program, when delivered via telehealth services?
Answer: Yes. CPT codes for administration of health risk assessment (96160 and 96161), outpatient visit for the evaluation and management for new (99201–99205) and established patients (99211–99215), transitional care management services (99495 and 99496), and advanced care planning (99497 and 99498) are included in the Medicare Shared Savings Program assignment methodology when delivered via telehealth. These codes were already established as able to be delivered via telehealth prior to the start of the COVID-19 PHE, so regardless of the waivers for place of service during the COVID-19 PHE, they are included in the Shared Savings Program assignment methodology**.**

When primary care services, as defined in 42 CFR § 425.400(c), are furnished and paid in accordance with Medicare fee-for-service payment policies, allowed charges for these services will be used in assignment in the Shared Savings Program.
Applicable Time Period: Performance Year 2020 and subsequent years
Updated: 3/5/21

33. **Question:** Does the Medicare Shared Savings Program (Shared Savings Program) extreme and uncontrollable circumstances policy for quality apply to all ACOs for performance year 2021?
Answer: Yes. The Public Health Emergency (PHE) for COVID-19 extends into performance year 2021. Consequently, CMS considers all ACOs affected by the COVID-19 PHE and the

Shared Savings Program extreme and uncontrollable circumstances policy applies for performance year 2021. ACOs that are able to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP) and meet MIPS data completeness and case minimum requirements, will receive the higher of their ACO quality score or the 30th percentile MIPS Quality performance category score. ACOs that are unable to report quality data via the APP and meet the MIPS Quality data completeness and case minimum requirements, will have their quality score set equal to the 30th percentile MIPS Quality performance category score.
Applicable Time Period: Performance Year 2021
New: 3/5/21

34. **Question:** Will CMS be conducting the Quality Measures Validation (QMV) Audit for the 2019 performance year for the Medicare Shared Savings Program ACOs?
Answer: CMS is continuing to evaluate the impact the COVID-19 PHE had on Shared Savings Program ACOs' quality reporting for the 2019 performance year in order to determine an approach for the QMV audit. At this time, we are reviewing the data reported by ACOs via the CMS Web Interface to determine if any data anomalies would require us to look at the data more closely via an audit, consistent with our current process. After completing this review, CMS may opt against conducting a QMV audit for the 2019 performance year. However, as provided in 42 CFR § 425.500(e), we retain the right to ask for additional information from ACOs or to conduct a targeted audit if egregious data anomalies are found.
Applicable Time Period: Performance Year 2019
New: 3/5/21

35. **Question:** For purposes of infection prevention and control, can ACOs remove the beneficiary notification posters in their facilities?
Answer: No, ACO participants cannot remove the beneficiary notification poster as CMS has not waived this requirement outlined in 42 CFR §425.312(a)(2)(i). We recommend that ACOs and their ACO participants follow detailed CDC guidance related to infection prevention and control found here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html and here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
New: 3/31/21

V. Cost Reporting

1. **Question:** Will CMS delay the filing deadline for cost reports impacted during the COVID-19 PHE?
Answer: Yes, 42 CFR 413.24 (f)(2)(ii) allows this flexibility. CMS will delay the filing deadline

of Fiscal Year End (FYE) 10/31/2019 and FYE 11/30/2019 cost reports until June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports until August 31, 2020. For the FYE 01/31/2020 cost report, the extended due date is August 31, 2020. For the FYE 02/29/2020 cost report, the extended due date is September 30, 2020. **For any cost reporting period not previously identified and ending on a date falling in the period of March 1, 2020 through December 31, 2020, providers are granted an additional 60 days from the initial due date to file their cost reports.**

In summary the extension impacts the following cost reporting fiscal year ends for all provider types (hospitals, SNFs, HHAs, hospices, ESRDs, RHCs, FQHCs, CMHCs, OPOs, histocompatibility labs and home office cost statements):

Cost Reporting Period Ending	Initial Due Date	Extended Due Date	Revised Due Date
10/31/2019	03/31/2020	06/30/2020	
11/30/2019	04/30/2020	06/30/2020	
12/31/2019	05/31/2020	07/31/2020	08/31/2020
01/31/2020	06/30/2020	08/31/2020	
02/29/2020	07/31/2020	09/30/2020	
For any cost reporting period not previously identified and ending on a date falling in the period of March 1, 2020 through December 31, 2020, providers are granted an additional 60 days from the initial due date to file their cost reports.			

Revised: 1/5/21

2. **Question:** How will the Provider Relief Fund (PRF) payments be reported on the Medicare Cost Report in terms of revenue?
   Answer: All providers must report the PRF payments on the cost report's statement of revenues for informational purposes. The revenue amount must be identified as COVID-19 PHE PRF. PRF payment amounts must be reported in aggregate on the following forms:
   - hospital, form CMS-2552-10, Worksheet G-3, line 24.50;
   - Skilled Nursing Facility, form CMS-2540-10, Worksheet G-3, line 24.50;
   - HHA, form CMS-1728-94, Worksheet F-1, line 31.50;
   - hospice, form CMS-1984-14, Worksheet F-2, column 3, line 16.50;
   - ESRD, form CMS-265-11, Worksheet F-1, line 31.50;
   - FQHC, form CMS-224-14, Worksheet F-1, line 28.50; and

- CMHC, form CMS-2088-17, Worksheet F, line 20.50

New: 8/26/20

3. **Question:** How will the Small Business Administration (SBA) Loan Forgiveness amounts be reported on the Medicare Cost Report in terms of revenue?
   Answer: If a provider receives forgiveness for the SBA loan, or any portion thereof, the provider must report the forgiven amount on the cost report's statement of revenues for informational purposes. The loan forgiveness amount must be reported in aggregate, on the same cost report forms, worksheets, and lines as noted above for the PRF payments in Question 1. If the provider does not receive forgiveness for the SBA loan, or any portion thereof, the provider reports no forgiven amounts on the Medicare cost report. If the provider pays interest on any portion of the SBA loan, the provider may report the interest expense, similar to other interest expenses, on the cost report.
   New: 8/26/20

4. **Question:** Should PRF payments offset expenses on the Medicare cost report?
   Answer: No, providers should not adjust the expenses on the Medicare cost report based on PRF payments received. However, providers must adhere to HRSA's guidance regarding appropriate uses of PRF payments, in order to ensure that the money is used for permissible purposes (namely, to prevent, prepare for, or respond to coronavirus, and for health care related expenses or lost revenues that are attributable to coronavirus) and that the uses of the PRF payments do not violate the prohibition on using PRF money to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.

   Recipients may find additional information on the terms and conditions of the PRF at https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/for-providers/index.html. Questions regarding use of the funds, pursuant to the Fund Terms and Conditions and any questions about overpayments should be directed to HRSA.
   New: 8/26/20

5. **Question:** Should SBA loan forgiveness amounts offset expenses on the Medicare cost report?
   Answer: No. Do not offset SBA Loan Forgiveness amounts against expenses unless those amounts are attributable to specific claims such as payments for the uninsured. The Paycheck Protection Program loan administered by the SBA is a loan designed to provide a direct incentive for small businesses to keep their workers on the payroll. The terms and conditions of the SBA loan forgiveness, overseen by the SBA, include employee retention criteria, and the funds must be used for eligible expenses.

Recipients may find additional information at https://www.sba.gov/funding-programs/loans/coronavirus-relief-options/paycheck-protection-program and https://home.treasury.gov/system/files/136/PPP--Loan-Forgiveness-FAQs.pdf.
New: 8/26/20

6. **Question:** Should hospitals report charges reimbursed through the PRF Uninsured Program on Worksheet S-10?
Answer: Subsection (d) hospitals that receive PRF payments from the Uninsured Program must not report charges reimbursed through that program for uninsured COVID-19 patients on Worksheet S-10 of the Medicare cost report.
New: 8/26/20

7. **Question:** Should PRF payment amounts for lost revenue not directly attributable to patient-specific claims be used to offset expenses on the Medicare cost report?
Answer: PRF payment amounts that are not attributable to patient-specific claims and are not PRF payment amounts from the Uninsured Program, should not be used to offset expenses on the Medicare cost report. Providers must adhere to HRSA's guidance regarding appropriate uses of PRF payments, in order to ensure that the money is used for permissible purposes (namely, to prevent, prepare for, or respond to coronavirus, and for health care related expenses or lost revenues that are attributable to coronavirus) and that the uses of the PRF payments do not violate the prohibition on using PRF money to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.
New: 8/26/20

8. **Question:** Can I claim my "employer's share of Social Security tax" that I elected to defer in accordance with section 2302 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, as an accrued liability in the year the costs were incurred?
Answer: Yes, in limited circumstances only. Section 2302 of the CARES Act provides that employers may defer the deposit and payment of the employer's portion of Social Security taxes and certain railroad retirement taxes (collectively referred to as the "employer's share of Social Security tax"). The deferral applies to deposits and payments of the employer's share of Social Security tax that would otherwise be required to be made during payroll tax deferral period that begins on March 27, 2020, and ends December 31, 2020. Providers that elect to take advantage of this payment deferral may expense this liability on the Medicare cost report in the year the costs were incurred in accordance with 42 CFR 413.100(c)(2)(i)(B), which states that *"if, within the 1-year time limit, the provider furnishes to the contractor sufficient written justification (based upon documented evidence) for nonpayment of the liability, the contractor may grant an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting period in which the liability was incurred."* Contractors may grant extensions for good cause for COVID-19-

related deferrals of the employer's share of Social Security taxes that were permitted under section 2302 of the CARES Act. Section 2302 of the CARES Act requires employers to deposit 50 percent of the deferred taxes on or before December 31, 2021, and the remaining 50 percent by December 31, 2022. However, if employers received loans under the Small Business Act and such loans were forgiven under section 1106 of the CARES Act, then such employers are not eligible for this deferral relief.

Disclaimer Language:
The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.
New: 8/26/20

W. Opioid Treatment Programs (OTPs)

1. **Question:** How are the add-on codes for take-home supplies of medication provided by opioid treatment programs billed?
   Answer: There are two codes that describe take-home dosages of medication:
   - HCPCS code G2078 — take-home supplies of methadone — describes up to 7 additional days of medication and is billed along with the respective weekly bundled payment in units of up to 3 (for a total of up to a one-month supply). This add-on code is only used with the methadone weekly episode of care code (HCPCS code G2067).
   - HCPCS code G2079 — take-home supplies of oral buprenorphine — describes up to 7 additional days of medication and is billed along with the base bundle in units of up to 3 (for a total of up to a 1-month supply). This add-on code is only used with the oral buprenorphine weekly episode of care code (HCPCS code G2068).

   New: 4/10/20

2. **Question:** What is the threshold for billing the weekly bundled payment codes for opioid treatment programs?
   Answer: The threshold to bill a full episode is that at least one service is furnished (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care. If no drug was provided to the patient during that episode, the OTP must bill the G-code describing a weekly bundle not including the drug (HCPCS code G2074) and the threshold to bill would be at least one service in the non-drug component. If a drug was provided with or without additional non-drug component services, the appropriate G-code describing the weekly bundle that includes the drug furnished may be billed.
   New: 4/10/20

3. **Question:** Will there be any changes to the rules for Opioid Treatment Programs (OTPs) billing the periodic assessment add-on code (HCPCS code G2077) during the COVID-19 public health emergency (PHE)?

Answer: Yes, in light of the PHE for the COVID-19 pandemic, in CMS-5531-IFC, CMS revised § 410.67(b)(7) on an interim final basis to allow periodic assessments (described by HCPCS code G2077) to be conducted via two-way interactive audio-video communication technology. In cases where the beneficiary does not have access to two-way interactive audio-video communication technology, the periodic assessment may be furnished using audio-only telephone calls.
New: 6/19/20

X. Inpatient Rehabilitation Facility Services

1. **Question:** If an IRF freestanding hospital or unit of a hospital accepts a patient solely in order to meet the demands of an emergency, will the patient be included in the freestanding hospital's or unit's inpatient population for purposes of calculating the applicable compliance thresholds at 42 CFR 412.29(b) ("the 60 percent rule")?
Answer: As a result of the COVID-19 emergency, and when an applicable section 1135 waiver is in effect, CMS will modify enforcement of the requirements specified in 42 CFR 412.29(b), which is the regulation commonly referred to as the "60 percent rule." Additional information regarding these requirements can be found in Chapter 3, Section 140.1.3 of the Medicare Claims Processing Manual (Pub. 100-04). If an IRF freestanding hospital or unit of a hospital admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such, the patient will not be included in the freestanding IRF hospital's or IRF unit's inpatient population for purposes of calculating the applicable compliance thresholds outlined in §412.29(b). In the case of an admission that is made solely to meet the demands of the emergency, the facility should clearly identify in the inpatient's medical record that the patient is being admitted solely to meet the demands of the emergency. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.
New: 4/10/20

2. **Question:** Is CMS waiving the IRF "3-hour rule"?
Answer: Yes. Section 3711(a) of the CARES Act requires the Secretary to waive 42 CFR 412.622(a)(3)(ii) (referred to as the "3-hour rule") during the public health emergency (PHE) period. This waiver was issued on April 15, 2020, at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf. This rule is waived for all IRF admissions during the PHE for the COVID-19 pandemic.
New: 6/19/20

3. **Question:** Can IRFs now admit patients that have some rehabilitation needs, but would not need/benefit from 3 hours of therapy per day and might only receive 1–2 hours of therapy per day?

Answer: Yes, the waiver required by section 3711(a) of the CARES Act waives the intensity of therapy requirement for all IRF patients during the public health emergency.
New: 6/19/20

4. **Question:** After the PHE has ended, will IRFs still be able to use the waiver of the "3-Hour Rule"?
   Answer: No, this waiver is only available during the PHE for the COVID-19 pandemic.
   New: 6/19/20

5. **Question:** What additional flexibilities is Medicare providing to IRFs to admit patients during the PHE who do not meet the IRF coverage or classification requirements?
   Answer: In the interim final rule with comment issued on April 30, 2020, CMS is temporarily modifying the classification and coverage criteria in 42 CFR 412.29(d), (e), (h), and (i) and § 412.622(a)(3)(i), (iii), (iv), (a)(4), and (a)(5) for care furnished to Medicare Part A fee-for-service patients who are admitted to a freestanding IRF in an area that is in Phase 1 or has not entered Phase 1 (see Guidelines for Opening Up America Again) solely to alleviate acute care hospital capacity during the PHE.
   New: 6/19/20

6. **Question:** Do these flexibilities apply for hospital-based IRFs as well?
   Answer: The waiver required by section 3711(a) of the CARES Act applies to IRF care in both freestanding and hospital-based IRFs during the PHE for COVID-19. However, CMS is temporarily modifying the classification and coverage criteria in 42 CFR 412.29(d), (e), (h), and (i) and § 412.622(a)(3)(i), (iii), (iv), (a)(4), and (a)(5) only for care furnished to Medicare Part A fee-for-service patients who are admitted to a freestanding IRF in an area that is in Phase 1 or has not entered Phase 1 (see Guidelines for Opening Up America Again) solely to alleviate acute care hospital capacity during the PHE. CMS believes that hospital-based IRFs, due to their affiliations with acute care hospitals, will be able to more easily alleviate bed capacity in those hospitals than freestanding IRFs.
   New: 6/19/20

7. **Question:** Do freestanding IRFs still need to comply with all requirements in 42 CFR 412.622(a)(3), (4), and (5) and § 412.29(d), (e), (h), and (i) for patients (not cared for solely to relieve acute care hospital capacity) during the PHE for the COVID-19 pandemic?
   Answer: With the exception of the "3-Hour Rule" (§ 412.622(a)(3)(ii)), freestanding and hospital-based IRFs must still comply with all other applicable regulations and requirements for Medicare Part A fee-for-service patients who are not admitted solely to relieve acute care hospital capacity.
   New: 6/19/20

8. **Question:** Will freestanding IRFs be paid under the inpatient perspective payment system or the IRF prospective payment system for patients admitted in areas that are in Phase 1 or have not entered Phase 1 (see Guidelines for Opening Up America Again) solely to relieve acute care hospital capacity during the PHE?
   Answer: With the changes implemented in the interim final rule with comment titled, "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-1744-IFC), freestanding IRFs can admit Medicare Part A fee-for-service patients under arrangements with the acute care hospitals to relieve acute care hospital bed capacity. The acute care hospitals will bill for the care provided to patients admitted in this way, and payment will be made under the inpatient prospective payment system. Alternatively, under the policy changes finalized in the interim final rule with comment issued on April 30, 2020, freestanding IRFs can admit Medicare Part A fee-for-service patients in areas that are in Phase 1 or have not entered Phase 1 (see Guidelines for Opening Up America Again) solely to relieve acute care hospital capacity during the PHE, document them as such in the IRF medical record, and receive payment under the IRF prospective payment system.
   New: 6/19/20

9. **Question:** How should freestanding IRFs designate which patients are cared for in areas that are in Phase 1 or have not entered Phase 1 (see Guidelines for Opening Up America Again) solely to alleviate acute care hospital capacity?
   Answer: IRFs must append the letters "DS" to the end of the patient's unique patient identifier number (the number that identifies the patient's medical records in the IRF) to identify Medicare Part A fee-for-service patients who are admitted to the freestanding IRF in areas that are in Phase 1 or have not entered Phase 1 (see Guidelines for Opening Up America Again) solely to alleviate acute care hospital bed capacity during the COVID-19 pandemic. The letters "DS" at the end of the patient's unique hospital identifier number will identify those Medicare Part A fee-for-service patients for whom the requirements in 42 CFR 412.622(a)(3)(i), (iii), (iv), (a)(4) and (a)(5) and § 412.29(d), (e), (h) and (i) do not apply.
   New: 6/19/20

10. **Question:** Will freestanding IRFs in all states (or regions, as applicable) be able to bill at the IRF PPS rate for patients who are admitted to the IRF solely to relieve acute care hospital capacity during the PHE for the COVID-19 pandemic?
    Answer: No, freestanding IRFs located in states (or regions, as applicable) that are in Phase 2 or Phase 3 of the White House's Guidelines for Opening Up America Again (https://www.whitehouse.gov/openingamerica/) at the time of admission will not be able to bill at the IRF PPS rate for patients who are admitted to the IRF solely to alleviate acute care hospital capacity. In this case, IRFs provide care under arrangements with the acute care hospitals, and Medicare pays for the services at the IPPS rate. Freestanding IRFs located in states (or regions, as applicable) that are in Phase 1 (or pending Phase 1) at the

time of admission will be able to bill at the IRF PPS rate for patients who are admitted to the IRF solely to relieve acute care hospital capacity during the PHE for COVID-19.
New: 6/19/20

Y. Skilled Nursing Facility Services

1. **Question:** Does the section 1812(f) waiver for the 3-day qualifying hospital stay apply only to those beneficiaries who are actually diagnosed with COVID-19, or does the waiver apply to all SNF-level beneficiaries under Medicare Part A?
   Answer: The qualifying hospital stay waiver applies to all SNF-level beneficiaries under Medicare Part A, regardless of whether the care the beneficiary requires has a direct relationship to COVID-19. See: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
   New: 4/10/20

2. **Question:** Can a Medicare Part A beneficiary who has exhausted his or her SNF benefits, but continues to need and receive skilled care in the SNF (e.g., for a qualifying feeding tube), renew SNF benefits under the section 1812(f) waiver regardless of whether or not the SNF or hospital was affected by the COVID-19 emergency?
   Answer: If the patient has a continued skilled care need (such as a feeding tube) that is unrelated to the COVID-19 emergency, then the beneficiary cannot renew his or her SNF benefits under the section 1812(f) waiver as it is this continued skilled care in the SNF rather than the emergency that is preventing the beneficiary from beginning the 60 day "wellness period." (https://www.cms.gov/files/document/coronavirus-snf-1812f-waiver.pdf)
   New: 4/10/20

3. **Question:** In order to help minimize unnecessary person-to-person contacts during the current PHE, is it permissible for clinical social workers (CSWs) to conduct their visits to Part A SNF residents remotely? If so, are such services subject to consolidated billing (CB, the SNF "bundling" requirement for services furnished during the course of a Medicare-covered stay)?
   Answer: The option to conduct their SNF visits remotely is always open to CSWs, regardless of whether a PHE is in effect. Moreover, the CB rules that apply to bundled services (such as CSW services that are furnished to a SNF's Part A resident) do not change merely because the services in question happen to be rendered remotely rather than in person; accordingly, such services when conducted remotely would remain subject to CB.
   New: 3/26/20

4. **Question:** Does waiving (pursuant to section 1812(f) of the Act) the requirement for a 3-day prior hospitalization for coverage of a SNF stay apply to swing-bed services furnished by CAHs and rural (non-CAH) swing-bed hospitals?
   Answer: Yes, under the section 1812(f) waiver, CAHs and rural (non-CAH) swing-bed

hospitals may furnish extended care services to a SNF-level patient even if the patient has not had a 3-day prior hospitalization in that or any other facility. The Social Security Act permits certain CAHs and rural (non-CAH) swing-bed hospitals to enter into a swing-bed agreement, under which the hospital can use its beds, as needed, to provide either acute or SNF care. Rural (non-CAH) hospitals are paid under the SNF PPS for their SNF-level swing-bed services. By contrast, CAH swing-bed services are not subject to the SNF PPS. Instead, Medicare pays CAHs based on 101 percent of reasonable cost for their swing-bed services. For additional information on swing-beds, see: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/SwingBed.
New: 4/10/20

5. **Question:** In order to help minimize unnecessary person-to-person contacts during the current public health emergency (PHE), is it permissible to provide therapy services to Part A SNF residents remotely? If so, are such services subject to consolidated billing (the SNF "bundling" requirement for services furnished during the course of a Part A Medicare-covered stay)?
   Answer: Yes, therapy services furnished to a Part A SNF resident may be furnished remotely during the COVID-19 PHE (consistent with state scope of practice laws), based on the clinical judgment of the therapist that the therapy being furnished is appropriate to be provided remotely and continues to meet the SNF level of care requirements. Moreover, the consolidated billing rules that apply to bundled services (such as therapy services that are furnished to a SNF's Part A resident) do not change merely because the services in question happen to be rendered remotely rather than in person; accordingly, such services when conducted remotely would remain subject to consolidated billing. Therapy services, such as those furnished by Physical Therapists, Occupational Therapists, and Speech Language Pathologists, to SNF residents who are not in a covered Part A SNF stay may be payable under the Part B Physician Fee Schedule, when reasonable and necessary. In these instances, PT, OT, and SLPs should follow the telehealth and CMS billing policies for Part B, including "Part B" consolidated billing, under which therapy services furnished to a SNF resident during a non-covered stay (Part A benefits exhausted, SNF level of care requirement not met, etc.), whether in person or by telehealth, must be billed to Part B by the SNF itself using bill type 22X.
   New: 6/19/20

6. **Question:** Can a positive COVID-19 test qualify a beneficiary (including a beneficiary who is currently receiving non-skilled services in a nursing home?) for a covered Medicare Part A skilled nursing facility (SNF) stay?
   Answer: A COVID-19 diagnosis would not in and of itself automatically serve to qualify a beneficiary for coverage under the Medicare Part A SNF benefit. That's because SNF coverage isn't based on particular diagnoses or medical conditions, but rather on whether the beneficiary meets the statutorily-prescribed SNF level of care definition of needing and

receiving skilled services on a daily basis which, as a practical matter, can only be provided in a SNF on an inpatient basis.
New: 6/19/20

7. **Question:** If a new benefit period was granted pursuant to the section 1812(f) waiver, and the PHE ends in the middle of that new benefit period, would the beneficiary be entitled to the full 100 days of renewed SNF benefits, or would that entitlement end on the day the PHE ends?
   Answer: If a beneficiary has qualified for the special one-time renewal of SNF benefits under the benefit period aspect of the section 1812(f) waiver while the section 1812(f) waiver is in effect, that reserve of 100 additional SNF benefit days would remain available for the beneficiary to draw upon even *after* the waiver itself has expired.
   New: 10/20/20

Z. General Billing Requirements

1. **Question:** Regarding the use of the condition code "DR" and modifier "CR", should these codes be used for all billing situations relating to COVID-19 waivers?
   Answer: Yes. With the exception of telehealth services, use of the "DR" condition code and "CR" modifier are mandatory for institutional and non-institutional providers in billing situations related to COVID-19 for any claim for which Medicare payment is conditioned on the presence of a "formal waiver" (as defined in the CMS Internet Only Manual, Publication 100-04, Chapter 38, §10). The DR condition code is used by institutional providers only, at the claim level, when all of the services/items billed on the claim are related to a COVID-19 waiver. The CR modifier is used by both institutional and non-institutional providers to identify Part B line item services/items that are related to a COVID-19 waiver. Medicare will not deny claims due to the presence of this condition code or modifier for services/items not related to a COVID-19 waiver.
   Revised: 4/23/20

2. **Question:** How will Medicare pay for COVID-19 testing administered prior to and in association with a procedure to be performed in a Medicare-enrolled setting, such as ambulatory surgical centers and independent freestanding emergency departments?
   Answer: CMS has not established national policy, either through rulemaking or a national coverage determination, regarding coverage of pre-procedure COVID-19 testing. Absent national policy, coverage of these tests are determined by the Medicare Administrative Contractors. Providers are reminded that all services provided must be reasonable and necessary and medical necessity must be documented in the medical record.
   New: 5/27/20

3. **Question:** If a beneficiary previously received testing for COVID-19, can the facility/practitioner be paid for retesting the beneficiary prior to the performance of the

procedure?
Answer: CMS has not established national policy, either through rulemaking or a national coverage determination, regarding coverage of pre-procedure COVID-19 testing. Absent national policy, coverage of these tests are determined by the Medicare Administrative Contractors. Providers are reminded that all services provided must be reasonable and necessary and medical necessity must be documented in the medical record.
New: 5/27/20

AA. Home Health

1. **Question:** For purposes of the statutory requirement that a patient have a face-to-face encounter with a physician or an allowed non-physician practitioner in order to qualify for Medicare home health care, can this encounter occur via telehealth during a pandemic outbreak of an infectious disease?
   Answer: The face-to-face encounter, as described at 1814(a)(2)(C) and 1835(a)(2)(A) of the Social Security Act, can be performed via telehealth in accordance with the requirements under 1834(m)(4)(C) of the Social Security Act. Under the expansion of telehealth under the 1135 waiver, beneficiaries are able to use telehealth technologies with their doctors and practitioners from home (or other originating site) for the face-to-face encounter to qualify for Medicare home health care.

   Please see the FAQs regarding the 1135 telehealth waiver at:
   https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf
   New: 5/1/20

2. **Question:** Can home health agencies furnish services using telecommunications technology during the PHE for the COVID-19 pandemic?
   Answer: Yes. Home health agencies are able to furnish services using telecommunications technology during the PHE as long as such services do not substitute for in-person visits ordered on the plan of care. This can include telephone calls (audio only and TTY), two-way audio-video telecommunications that allow for real-time interaction between the patient and clinician (e.g., FaceTime, Skype), and remote patient monitoring. It would be up to the clinical judgment of the home health agency and patient's physician/practitioner as to whether such technology can meet the patient's need. The use of telecommunications technology in furnishing services under the home health benefit must be included on the plan of care and the plan of care must outline how such technology will assist in achieving the goals outlined on the plan of care.
   New: 5/1/20

3. **Question:** Can home health agencies include services furnished using telecommunications technology on the home health claim that it submits to Medicare for payment?

Answer: Only in-person visits are to be reported on the home health claim submitted to Medicare for payment. On an interim basis, HHAs can report the costs of telecommunications technology on the HHA cost report as allowable administrative and general (A&G) costs by identifying the costs using a subscript between line 5.01 through line 5.19.
New: 5/1/20

4. **Question:** Can ordering clinician include "as needed" or "when necessary" (commonly abbreviated as PRN) on the orders for the home health plan of care for telecommunications encounters in the event the patient chooses not to have in-person visits by home care nurse?
   Answer: If an HHA anticipates that there may be the need for "PRN" telecommunications encounters (including telephone calls) for the purposes of providing a skilled service, these "PRN" orders can be included on the home health plan of care similar to how "PRN" orders for in-person visits would be included. That is, orders for services to be provided "as needed" or "PRN" must be accompanied by a description of the beneficiary's medical signs and symptoms that would occasion the visit and a specific limit on the number of those visits to be made under the order before an additional physician order would have to be obtained. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. If a range of visits is ordered, the upper limit of the range is considered the specific frequency under 42 CFR §409.43(b).
   New: 5/1/20

5. **Question:** Can home health agencies complete the initial assessments virtually or over the phone during the PHE for the COVID-19 pandemic?
   Answer: Yes. CMS has waived the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely, by phone, or by record review. This will allow patients to be cared for in the best environment for them while supporting infection control and reducing impact on acute care and long- term care facilities. This will also allow for maximizing coverage by already scarce physician and advanced practice clinicians and allow those clinicians to focus on caring for patients with the greatest acuity.
   New: 5/1/20

6. **Question:** Can home health agencies complete the comprehensive assessment and updates to the comprehensive assessment virtually or over the phone during the PHE for the COVID-19 pandemic?
   Answer: Utilizing telecommunications technology is an option for the completion of the comprehensive assessment and the update of the comprehensive assessment. HHAs can provide services to beneficiaries using telecommunications technology (which can include audio-only or TTY telephone calls, or two-way audio-video telecommunications technology,

like FaceTime or Skype) so long as it's part of the patient's plan of care and does not substitute for in-person visits as ordered on the plan of care. We acknowledge that the use of such technology may result in changes to the frequency or types of in-persons visits outlined on existing or new plans of care. The plan of care should be modified to reflect which visits will be made in person, and which visits will be conducted via telecommunications technology.

While we have provided certain flexibilities, the regulations require HHAs to have an infection prevention and control program, and to educate patients about infection prevention and control in the home. As such, we expect HHAs to make every effort to educate patients as to what processes the HHA has in place to protect patients as well as home care staff. While there are some aspects of care that can be done via telecommunications technology, not everything can be accomplished by telecommunications technology when skilled care is required. The HHA will have to work closely with the patient to determine what would help to reassure them that visits from HHA staff are safe. If the patient continues to refuse any in-person visits as per the plan of care, including assessment or other patient care visits, the HHA will have to determine if the HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence per 42 CFR §484.60.
New: 5/1/20

7. **Question:** Section 3708 of the CARES Act made changes regarding who is able to certify beneficiaries for eligibility and order services under the home health benefit. Who can now perform these services?
   Answer: "Allowed practitioners" in addition to physicians, can now certify beneficiaries for eligibility, order home health services, and establish and review the care plan. Allowed practitioners are defined at 42 CFR 484.2 as physician assistants, nurse practitioners, or clinical nurse specialists as defined elsewhere in 42 C.F.R. Part 484. The definitions for such practitioners are aligned with existing definitions in regulation at §§ 410.74– 410.76, for consistency across the Medicare program and to ensure that Medicare home health beneficiaries are afforded the same standard of care. In general, nurse practitioner (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) are required to practice in accordance with state law in the state in which the individual performs such services. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required.
   New: 6/19/20

8. **Question:** How can home health agencies ensure that allowed practitioners are practicing in accordance with state law?

Answer: Home health agencies or other practitioners should check with the relevant state licensing authority websites to ensure that practitioners are working within their scope of practice and prescriptive authority.
New: 6/19/20

9. **Question:** When can physician assistants, nurse practitioners, and clinical nurse specialists begin certifying and ordering care for patients under the home health benefit?
Answer: Physician assistants, nurse practitioners, and clinical nurse specialists working in accordance with State Law can begin certifying, re-certifying beneficiaries for eligibility, ordering home health services, and establishing and overseeing plans of care under the Medicare home health benefit beginning with dates of service of March 1, 2020, or later, and home health services can begin billing for these services, for 30-day periods of care with "claim through dates" of March 1, 2020, or later.
New: 6/19/20

10. **Question:** How can physician assistants, nurse practitioners, and clinical nurse specialists' bill for the work involved with certifying/recertifying patient eligibility for home health care and for care plan oversight while the patient is receiving home health services?
Answer: These practitioners can bill for services using the G-codes: G0179, G0180, and G0181. Although these code descriptions still indicate they are physician codes, allowed practitioners, as defined at 42 CFR 484.2 can begin billing them for dates of service on or after March 1, 2020. Further information will be forthcoming in an upcoming edition of MLN Connects.
New: 6/19/20

11. **Question:** Are other non-physician practitioner types, such as certified nurse midwives, considered "allowed practitioners"?
Answer: Pursuant to the statutory language set out at section 3708 of the CARES Act, "allowed practitioners" are only physician assistants, nurse practitioners, and clinical nurse specialists for the purpose of certifying and ordering home health services and establishing the plan of care. Section 3708 of the CARES Act does not give CMS the authority to allow other non-physician practitioners, such as nurse midwives, to certify and order home health services; however, as set out at 42 CFR 424.22(a)(1)(v)(A), they may continue to perform the face-to-face encounter.
New: 6/19/20

12. **Question:** Will the changes to allow NPs, CNSs and PAs to order and certify patients for eligibility under the Medicare home health benefit be permanent or only during the Public Health Emergency for COVID-19?
Answer: This IFC makes permanent changes to sections 1814(a) and 1835(a) of the Act, pursuant to section 3708 of the CARES Act, to allow NPs, CNSs, and PAs, to order and certify

patients for eligibility under the Medicare home health benefit.
New: 6/19/20

13. **Question:** Can a nurse practitioner, physician assistant, or clinical nurse specialist sign the home health recertification statement and the plan of care in place of a physician or another allowed practitioner?
Answer: The home health conditions of participation do not prohibit home health agencies (HHAs) from accepting orders from multiple physicians, and now with the recent statutory change, nurse practitioners, physician assistants, and clinical nurse specialists (i.e., allowed practitioners). The HHA is ultimately responsible for the plan of care, which includes assuring communication with all physicians and allowed practitioners involved in the plan of care and integrating orders from all physicians/allowed non-physician practitioners involved in the plan to assure the coordination of all services and interventions provided to the patient. This responsibility extends to a physician or other allowed non-physician practitioner, other than the certifying physician or allowed non-physician practitioner who established the home health plan of care, who signs the plan of care or the recertification statement in the absence of the certifying physician or allowed non-physician practitioner. This is only permitted when such physician or non-physician practitioner has been authorized to care for his/her patients in his/her absence. The HHA is responsible for ensuring that the physician or allowed non-physician practitioner who signs the plan of care and recertification statement was authorized by the physician or allowed non-physician practitioner who established the plan of care and completed the certification for his/her patient in his/her absence. Our regulations at 42 CFR 424.22(a)(1)(v)(A) require that the physician or allowed practitioner that performed the required face-to-face encounter also sign the certification of eligibility, unless the patient is directly admitted to home health care from an acute or post-acute care facility and the encounter was performed by a physician or allowed practitioner in such setting.
New: 6/19/20

BB. Drugs & Vaccines under Part B

1. **Question:** Will Medicare Part B pay for COVID-19 vaccinations of Medicare beneficiaries?
Answer: Yes. The CARES Act includes a provision that establishes Part B coverage for COVID-19 vaccines and their administration without any cost-sharing. Because it will be covered under Part B, the COVID vaccine and its administration will not be covered under Part D.
New: 4/10/20

2. **Question:** If new drugs are approved to treat COVID-19, can they be billed?
Answer: New drugs that are covered under Medicare Part B, including new antiviral drugs, can be paid by the Medicare Administrative Contractors once they receive a code and are on the pricing files.
Posted: 3/6/20

3. **Question:** Will Medicare Part B cover an extended supply of drugs during a pandemic or similar emergency, when such drugs are needed for a patient's chronic condition?
Answer: For Part B drugs, when considering whether to pay for an extended supply of drugs, Medicare and its contractors, known as Medicare Administrative Contractors or MACs, will make decisions locally. In general, local Medicare contractors will take into account the nature of the particular Part B drug (including Part B immunosuppressive drugs), the patient's diagnosis, the extent and likely duration of disruptions to the drug supply chain during an emergency, and other relevant factors that would be applicable when making a determination as to whether, on the date of service, an extended supply of the drug was reasonable and necessary. Information on payment for extended supplies of Part B drugs in special circumstances is made available by the local MAC that processes a provider or supplier's drug claims.

   Please see Fact Sheet posted at: https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf
   New: 3/26/20

4. **Question:** If a Medicare-enrolled provider or supplier receives drugs or supplies (including testing supplies) from the Strategic National Stockpile (SNS) or other drugs or supplies procured or provided by a governmental entity, what are the Medicare billing rules? How should these providers and suppliers handle billing for services and supplies that involve the use of SNS or other federally provided drugs or supplies?
Answer: A provider or supplier's use of drugs or supplies procured or provided by a governmental entity to diagnose or treat patients with known or suspected COVID-19 would not affect Medicare's payment for the service under the applicable prospective payment system or fee schedule. Although Medicare usually doesn't allow payment for services that are paid for by a governmental entity, there is an exception for services furnished as a means of controlling infectious diseases (see 42 CFR § 411.8(b)(4)). However, providers and suppliers should not seek additional payment on the claim for these drugs or supplies, as described in the CMS Internet Only Manual, Pub. 100-04, Chapter 32, Section 67. In addition, providers and suppliers that submit Medicare cost reports should not reflect the costs of free drugs or supplies on their cost reports. In contrast, providers and suppliers should follow ordinary billing rules for drugs or supplies purchased from governmental entities.
   Revised: 7/28/20

5. **Question:** Will Medicare pay for monoclonal antibody products to treat COVID-19 and their administration under Part B? Could monoclonal antibody products authorized under an Emergency Use Authorization (EUA) to treat COVID-19 be paid for under Medicare Part B, if so, how?

Answer: Yes, in order to ensure immediate access during the COVID-19 public health emergency (PHE), Medicare will pay for monoclonal antibody products authorized for emergency use to treat COVID-19, furnished consistent with the terms of the EUA, or approved by the Food and Drug Administration (FDA) to treat COVID-19. Medicare payment for monoclonal antibody products for the treatment of COVID-19 will be in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). As of early May 2021, two monoclonal antibody products had active FDA EUAs: one for casirivimab and imdevimab (administered together), and one for bamlanivimab and etesevima (administered together).[3] On April 16, 2021, the FDA revoked the EUA for bamlanivimab. Medicare will no longer pay for the administration of bamlanivimab when that product is administered by itself. Should the FDA authorize or approve additional monoclonal antibodies for the treatment of COVID-19, the same Medicare payment policies would apply.

Health care providers who furnish these services to enrollees in a Medicare Advantage (MA) plan should submit claims for monoclonal antibodies to treat COVID-19 that are covered by Part B, in accordance with Section 3713 of the CARES Act, to Original Medicare for all patients enrolled in MA in 2020 and 2021.

Medicare will make a payment to the provider or supplier for the monoclonal antibody product to treat COVID-19 (when it is not received by the provider for free) and will make a separate payment for its administration (infusion). Medicare will not provide payment for the monoclonal antibody products to treat COVID-19 that health care providers receive for free, as will be the case upon the product's initial availability in response to the COVID-19 PHE. Because these monoclonal antibody products are being paid under the COVID-19 vaccine benefit, they are not eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS).

While physicians and other Medicare providers and suppliers cannot bill Medicare for the product they receive for free, they may be paid for its administration. For monoclonal antibodies furnished through May 5, 2021, the Medicare national average payment rate[4] for the administration was approximately $310 for the infusion of bamlanivimab,[5] casirivimab and imdevimab (administered together) or bamlanivimab and etesevima (administered together). This preliminary payment rate was based on one hour of infusion and post-infusion monitoring in the hospital outpatient setting. Medicare announced that for

[3] Casirivimab and Imdevimab FDA EUA: https://www.fda.gov/media/143891/download (they are administered together) / Bamlanivimab and etesevima FDA EUA: https://www.fda.gov/media/145801/download (they are administered together)

[4] For more information please visit: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

[5] On April 16, 2021, the FDA revoked the EUA for bamlanivimab. Medicare will no longer pay for the administration of bamlanivimab when that product is administered by itself.

monoclonal antibodies furnished on or after May 6, 2021, the national average payment rate will be increased to $450 per administration. In addition, Medicare also announced a new national average payment rate of $750 when providers or suppliers furnish monoclonal antibodies in the home or residence on or after May 6, 2021.

When health care providers begin to purchase monoclonal antibody products, CMS anticipates setting the Medicare payment rate in the same way we anticipate setting the payment rate for COVID-19 vaccines.

See the chart below for how the payment rates are established by setting type for COVID-19 vaccine products and their administration. CMS intends to address potential refinements to payment for these monoclonal antibody products and their administration through future notice and comment rulemaking.
Updated: 5/6/21

6. **Question:** How long will Medicare pay for monoclonal antibody COVID-19 products to treat COVID-19 and their administration under Part B?
   Answer: In order to ensure immediate access during the COVID-19 PHE, Medicare will pay for monoclonal antibody products to treat COVID-19 in accordance with Section 3713 of CARES Act. That is, during the COVID-19 PHE, Medicare will cover and pay for these infusions, when furnished consistent with the EUA, in the same way it covers and pays for other COVID-19 vaccines.
   Updated: 5/6/21

7. **Question:** What are the different payment amounts for monoclonal antibody products to treat COVID-19 and their associated administration across health care settings?
   Answer: In order to ensure immediate access during the COVID-19 PHE, Medicare will pay for monoclonal antibody products to treat COVID-19 in accordance with Section 3713 of the CARES Act. That is, during the COVID-19 PHE, Medicare will cover and pay for these infusions, when furnished consistent with the FDA EUA or approval, the same way it covers and pays for other COVID-19 vaccines. CMS intends to address potential refinements to payment for these monoclonal antibody products and their administration through future notice and comment rulemaking.

   Medicare will make a payment to the provider or supplier for the monoclonal antibody product to treat COVID-19 (when the product is not received by the provider for free) and make a separate payment for its administration (infusion). Medicare will not pay for the monoclonal antibody products to treat COVID-19 that health care providers receive for free, as will be the case upon the product's initial availability in response to the COVID-19 PHE. If health care providers begin to purchase these monoclonal antibody products, CMS anticipates setting the Medicare payment rate for the product, which will be reasonable

cost or 95% of the average wholesale price for many health care providers, consistent with usual vaccine payment methodologies.

While physicians and other Medicare providers and suppliers cannot bill Medicare for the product they receive for free, they may be paid for its administration. For monoclonal antibodies furnished through May 5, 2021, the Medicare national average payment rate[6] for the administration was approximately $310 for the infusion of bamlanivimab,[7] casirivimab and imdevimab (administered together) or bamlanivimab and etesevima (administered together). This preliminary payment rate was based on one hour of infusion and post-infusion monitoring in the hospital outpatient setting. Medicare announced that for monoclonal antibodies furnished on or after May 6, 2021, the national average payment rate will be increased to $450 per administration. In addition, Medicare also announced a new national average payment rate of $750 when providers or suppliers furnish monoclonal antibodies in the home or residence on or after May 6, 2021.

A list of Medicare providers and suppliers and the corresponding payment rate for COVID-19 vaccines and their administration is below. Medicare will cover and pay for these infusions in these settings when furnished consistent with each product's FDA EUA or approval, and in accordance with any state scope of practice and licensure requirements.

Medicare Provider/Supplier[8]	**Vaccine Payment Rate[9]**	**Vaccine Administration Payment[10]**
Physician Offices	95% Average Wholesale Price	Paid separately using the established rate for the applicable administration code
Hospitals: Outpatient Departments	Reasonable Cost[11]	Paid separately using the established rate for the applicable administration

[6] For more information please visit: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

[7] On April 16, 2021, the FDA revoked the EUA for bamlanivimab. Medicare will no longer pay for the administration of bamlanivimab when that product is administered by itself.

[8] Currently enrolled providers and suppliers may contact their MAC to furnish and bill for these items and services. Additional provider enrollment information, can be accessed here: https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots

[9] These rates apply only when the provider or supplier does not receive the product for free. Medicare will not provide payment for the monoclonal antibody products that health care providers receive for free.

[10] As of November 10, 2020, the established Medicare national average payment rate for the infusion of the bamlanivimab product to treat COVID-19 is roughly $310, unless otherwise noted. This payment rate is based on one hour of infusion in the hospital outpatient setting. See applicable administration codes in question below.

[11] Reasonable cost means cost actually incurred, to the extent that cost is necessary for the efficient delivery of the service, and subject to the exclusions specified in paragraph 42 CFR 413.13(d).

		code. Reasonable cost for hospitals not subject to the Outpatient Prospective Payment System.
Hospitals: Inpatient	Reasonable Cost	Paid separately using the established rate for the applicable administration code.
Skilled Nursing Facilities	Reasonable Cost	Paid separately using the established rate for the applicable administration code.
Home Health Agencies	Reasonable Cost	Paid separately using the established rate for the applicable administration code.
Critical Access Hospitals (CAHs)	101% of Reasonable Cost	101% of Reasonable cost
Long-Term Care Hospitals	Reasonable Cost	Paid separately using the established rate for the applicable administration code.
Inpatient Rehabilitation Facilities	Reasonable Cost	Paid separately using the established rate for the applicable administration code.
Federally Qualified Health Centers & Rural Health Centers	Paid through the cost report process	Paid through the cost report process
Indian Health Service Hospitals & CAHs	95% Average Wholesale Price	Paid separately using the established rate for the applicable administration code.
Hospice	95% Average Wholesale Price	Paid separately using the established rate for the applicable administration code.
Home Infusion Therapy Suppliers	95% Average Wholesale Price	Paid separately using the established rate for the applicable administration code.

Updated: 5/6/21

8. **Question:** What is the new Medicare payment rate for COVID-19 monoclonal antibody products administered in a patient's home or residence?
Answer: Beginning on May 6, 2021, Medicare established separate coding and payment for administering COVID-19 monoclonal antibody products in a patient's home or residence. Effective for services furnished on or after May 6, 2021, the new Medicare payment rate for administering monoclonal antibody products in a patient's home or residence is approximately $750. This rate reflects updated information about the costs involved in furnishing these complex products in a patient's home. For many providers and suppliers this rate is geographically adjusted based on the locality in which the service is furnished.

   Providers and suppliers may bill for the higher home payment rate when they furnish a COVID-19 monoclonal antibody product in a "home or residence," which includes circumstances, such as a beneficiary's permanent residence, temporary lodging (e.g., hotel/motel, cruise ship, hostel, or homeless shelter) and homes or residences that have been made provider-based to the hospital during the COVID-19 PHE. Providers and suppliers administering COVID-19 monoclonal antibodies to beneficiaries in traditional health care locations (e.g., hospital outpatient infusion clinic or freestanding infusion clinic) should continue to bill HCPCS codes M0243 or M0245 as applicable. Get the most current list of billing codes, payment allowances, and effective dates for currently authorized monoclonal antibody products.
   Updated: 5/6/21

9. **Question:** Which billing codes should be used for submitting claims for the monoclonal antibody COVID-19 products? What is the payment rate associated with those codes?
Answer: CMS makes Level II HCPCS codes for monoclonal antibody products to treat COVID-19 and their administration (e.g., infusion) available shortly after they are authorized or approved by the FDA. The current list of Level II HCPCS codes for monoclonal antibodies to treat COVID-19, the corresponding codes for administration, and associated effective dates is maintained at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

   CMS has released HCPCS codes for the monoclonal antibody for COVID-19 casirivimab and imdevimab (administered together) and bamlanivimab and etesevima (administered together).
   - Casirivimab and imdevimab: Product – HCPCS Q0243/ Administration – HCPCS M0243 / Administration in the home or residence – HCPCS M0244
   - Bamlanivimab and etesevima: Product – HCPCS Q0245 / Administration – HCPCS M0245 / Administration in the home or residence – HCPCS M0246

For specific instructions on how to bill the Medicare program for monoclonal antibody treatments, please see the monoclonal antibody program instruction here: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

Quarterly HCPCS Coding updates are posted here: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.
Updated: 5/6/21

10. **Question:** What is the cost-sharing obligation for Medicare beneficiaries?
    Answer: There is no beneficiary cost sharing and no deductible for monoclonal antibody COVID-19 products to treat COVID-19 when administration is provided in a Medicare-enrolled care setting by a Medicare-enrolled provider or supplier (consistent with Section 3713 of the CARES Act).
    Updated: 5/6/21

11. **Question:** If for Medicare payment purposes Medicare is treating monoclonal antibody products to treat COVID-19 as Part B vaccines, how will entities that are paid for such vaccines under a cost-based methodology be paid?
    Answer: Many institutional providers are paid "reasonable cost" for vaccines. See the chart in the above questions for a list of Medicare providers and suppliers and the corresponding payment rate for COVID-19 vaccines and their administration.
    Updated: 5/6/21

12. **Question:** Will mass immunizers be able to furnish and bill for monoclonal antibodies and their administration?
    Answer: Yes, similar to other COVID-19 vaccines, mass immunizers will be able to furnish and bill for monoclonal antibodies to treat COVID-19 and their administration, consistent with the product's EUA and in accordance with state law and scope of practice
    New: 5/6/21

13. **Question:** Will Medicare pay specialty pharmacies for obtaining and preparing the monoclonal antibodies for use by another provider or supplier?
    Answer: As noted in other questions and answers above, Medicare will cover and pay for monoclonal antibody infusions to treat COVID-19, when furnished consistent with the EUA, the same way it covers and pays for other COVID-19 vaccines. Medicare will make a payment for the monoclonal antibody product to treat COVID-19 to the provider or supplier that furnished it (when the product is not received by the provider for free) and make a separate payment for its administration (infusion). Medicare will not provide payment for the monoclonal antibody products to treat COVID-19 that health care providers receive for free, as will be the case upon the product's initial availability in response to the COVID-19

PHE.

Medicare will not make separate payment for the preparation of monoclonal antibodies for use by another provider or supplier, including in cases where the product is provided free of charge to specialty pharmacies that prepare the product prior to infusion. The enrolled provider or supplier that administers (infuses) the product to the patient would bill for the administration and would be eligible for payment for the administration, but would not receive payment if the actual product was provided to an entity free of charge (see previous FAQs for the Medicare administration payment amount).

If health care providers begin to purchase monoclonal antibody COVID-19 products, CMS anticipates setting the Medicare payment rate for the product, which will be reasonable cost or 95% of the average wholesale price for many health care providers, consistent with usual Part B vaccine payment methodologies (please see chart in earlier question). For specific instructions on how to bill the Medicare program for monoclonal antibody treatments, please see the monoclonal antibody program instruction here: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf.
Updated: 5/6/21

14. **Question:** What documentation is a health care provider or supplier expected to maintain when they bill Medicare for monoclonal antibody COVID-19 treatments and their administration?
Answer: Medicare will pay for monoclonal antibody products authorized for emergency use to treat COVID-19, furnished consistent with the terms of the EUA, or approved by the FDA to treat COVID-19. The EUAs for COVID-19 monoclonal antibodies contain specific requirements for administration that are considerably more complex than for other services that are billed using roster billing. CMS expects that health care providers will maintain appropriate medical documentation that supports the medical necessity of the service. This includes documentation that supports that the terms of the applicable EUA are met, including that it is being used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) for a patient that is at high risk for progressing to severe COVID-19 and/or hospitalization. The documentation should also include the name of the practitioner who ordered or made the decision to administer the infusion, even in cases where claims for these services are submitted on roster bills.
Updated: 5/6/21

15. **Question:** CMS has established flexibilities under the Hospital Without Walls initiative to allow hospitals to furnish care in temporary expansion sites, including erected tents, retrofitted convention centers and beneficiaries' homes. Would hospitals also be able to use these same flexibilities to furnish monoclonal antibodies in temporary expansion sites?

Answer: In response to the COVID-19 PHE, CMS issued several 1135 waivers of certain hospital conditions of participation and the provider-based rules, in order to allow hospitals to furnish hospital services, including drug infusion, in temporary expansion sites. These Hospital Without Walls flexibilities permit hospitals to furnish any reasonable and necessary treatments, including monoclonal antibodies, in temporary expansion sites, such as an erected tent, a retrofitted convention center, or the beneficiary's home, consistent with the terms of each product's EUA or FDA approval, as applicable. Hospitals that previously constructed expansion sites at the beginning of the PHE, and were approved under earlier 1135 waivers, are able to continue using those sites so long that they continue to meet the conditions of participation that remain in effect during the COVID-19 PHE.

Effective for services furnished on and after May 6, 2021, Medicare announced a new national average payment rate of $750 when providers or suppliers furnish monoclonal antibodies in the home or residence. We note that hospital outpatient departments may bill for this higher payment when a) the hospital has made the patient's home provider-based to the hospital under the Hospital Without Walls flexibility and b) the hospital furnishes monoclonal antibodies may to the beneficiary in that location.

More information about the Hospitals Without Walls flexibilities and the temporary extraordinary circumstances relocation exception can be found here.
New: 5/6/2021

16. **Question:** Under Section 603 of the Bipartisan Budget Act of 2015, new off-campus provider-based departments (PBDs) that start billing Medicare under the OPPS after November 2, 2015, are considered "non-excepted" and are paid for items and services under the "applicable payment system" rather than the Outpatient Prospective Payment System (OPPS). CMS determined that the Medicare Physician Fee Schedule (PFS) was the applicable payment system for applicable services billed by non-excepted departments. Effective since 2018, the PFS Relativity Adjuster that applies to these services is 40 percent of the OPPS rate. Will the applicable payment system apply to payments for monoclonal antibody products used to treat COVID-19 and their administration when performed by non-excepted PBDs?
Answer: Payment for monoclonal antibody COVID-19 products and their administration will be at the same rate as the full OPPS payment when furnished by non-excepted off-campus PBDs. This means that the 40% PFS relativity adjuster does not apply in this circumstance.
Updated: 5/6/21

17. **Question:** How will Skilled Nursing Facilities and other entities be paid by Medicare for monoclonal antibody products to treat COVID-19 furnished to Medicare beneficiaries?
Answer: During the PHE, Medicare Part B will cover and pay for monoclonal antibody products authorized for emergency use to treat COVID-19, when furnished consistent with

the product's EUA, or approved by the FDA to treat COVID-19, in accordance with Section 3713 of the CARES Act; that is, during the COVID-19 PHE, Medicare will cover and pay for these infusions, when furnished consistent with the EUAs, in the same way it covers and pays for COVID-19 vaccines. Medicare will not provide payment for monoclonal antibody products to treat COVID-19 that health care providers receive for free, as we anticipate will be the case upon the product's initial availability in response to the COVID-19 PHE. If providers begin to purchase these monoclonal antibody products during the COVID-19 PHE, Medicare will pay for these products furnished to beneficiaries the same way it pays for other COVID-19 vaccines.

Any entity that can bill Medicare for Part B vaccines can bill Medicare for these infusions, so long as it is administered in a manner consistent with the product's EUA or FDA approval to treat COVID-19. Medicare will make a payment to the health care providers, like Skilled Nursing Facilities, for the monoclonal antibody product to treat COVID-19 when the product is not received by the provider for free, and will make a separate payment for its administration (infusion) under Medicare Part B.

If you are an entity that is not currently able to furnish and bill for infusions based on your Medicare enrollment status and wish to administer monoclonal antibody products to treat COVID-19 (in accordance with each product's EUA), you can follow the enrollment information provided for vaccine providers found here: https://www.cms.gov/covidvax-provider. The same enrollment process for entities wishing to enroll as a COVID-19 vaccine provider will apply for entities wishing to administer monoclonal antibody treatments to treat COVID-19.

See previous FAQs for the specific Medicare payment rates as updated on May 6, 2021.
Updated: 5/6/21

18. **Question:** Does SNF Consolidated Billing preclude outside entities from billing Part B directly for furnishing monoclonal antibody products to treat COVID-19 to Part A SNF residents?
Answer: No. In order to facilitate the efficient administration of COVID-19 vaccines and COVID-19 monoclonal antibody treatments to SNF residents, CMS will exercise enforcement discretion (as discussed at https://www.cms.gov/medicare/covid-19/snf-enforcement-discretion-relating-certain-pharmacy-billing) with respect to statutory provisions requiring consolidated billing by SNFs as well as any associated statutory references and implementing regulations, including as interpreted in pertinent guidance. Through the exercise of that discretion, CMS will allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law, including, but not limited to, pharmacies working with the United States, as well as infusion centers, and home health agencies, to bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments to Medicare Part A SNF residents. This

enforcement discretion, and accordingly the ability for entities other than the SNF to submit claims for these monoclonal antibody products and their administration furnished to Medicare Part A SNF residents, is limited to the period described in the above-cited enforcement discretion notice.

If you are an entity that is not currently able to furnish and bill for infusions based on your Medicare enrollment status and wish to administer monoclonal antibody products to treat COVID-19 (in accordance with the each product's EUA), you can follow the enrollment information provided for vaccine providers found here: https://www.cms.gov/covidvax-provider. The same enrollment process for entities wishing to enroll as a COVID-19 vaccine provider will apply for entities wishing to administer monoclonal antibody treatments to treat COVID-19.
New: 5/6/21

19. **Question:** Can Home Health Agencies (HHAs) and Home Infusion Therapy (HIT) suppliers furnish and bill for the administration of monoclonal antibody treatments?
Answer: Yes, subject to applicable state law, HHAs and HIT suppliers working within their scope of practice may bill for the monoclonal antibody products to treat COVID-19 and their administration, when furnished consistent with the EUA, for the duration of the PHE. We note that HIT suppliers must be enrolled as a "mass immunizer" in order to separately bill Medicare for these products and their administration. During the PHE, Medicare will cover and pay for these infusions in accordance with Section 3713 of the CARES Act and thus pay for them in the same way it covers and pays for other COVID-19 vaccines (when furnished consistent with the product's EUA). A Medicare-enrolled HHA does not need to take any action to administer and bill for monoclonal antibody products to treat COVID-19 and their administration, either through individual claims or roster billing, as home health agencies can already separately bill for vaccines. A Medicare-enrolled HIT supplier should also enroll as a mass immunizer and bill Medicare accordingly. More information on the mass immunizer enrollment process can be found here: https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots.

See previous FAQs for the specific Medicare payment rates the administration of COVID-19 monoclonal antibody treatments administered in a patient's home or residence.
New: 5/6/21

20. **Question:** Can physicians and non-physician practitioners furnish and bill Medicare for evaluation and management (E/M) services on the same day that the patient receives an infusion of monoclonal antibodies? Similarly, can hospital outpatient departments furnish office visit services on the same day the patient receives an infusion of monoclonal antibodies?
Answer: CMS understands that many providers and suppliers are still developing the

optimal model to ensure patients with COVID-19 receive monoclonal antibodies in the timeliest fashion, since early evidence indicates they work better the earlier they are furnished. It is possible that physicians and non-physician practitioners may conduct an office visit for a patient, test the patient for COVID-19, obtain a positive diagnosis, and ensure the patient receives an infusion of monoclonal antibodies all in the same day. It is our intention to support these kinds of models that speed the time from diagnosis to infusion, as they could ensure more beneficiaries receive effective treatment with reduced morbidity and mortality.

Under current policy, if a physician or non-physician practitioner sees a beneficiary for the sole purpose of administering a vaccine (including a COVID-19 monoclonal antibody treatment), they may not routinely bill for an E&M visit. However, physicians and non-physician practitioners can bill for an E&M service furnished on the same day as a vaccine (including a COVID-19 monoclonal antibody treatment) when the practitioner performs a medically necessary and significant, separately identifiable E&M visit in addition to the vaccine administration. During the PHE, we would anticipate this circumstance to be a common occurrence, and physicians and non-physician practitioners furnishing these services on the same day should add modifier "25" to the E&M code to identify it as a medically necessary E&M service furnished on the same day that another service is furnished by the same physician or other supplier. Similarly, hospital outpatient departments furnishing separately identifiable office visits on the same day a vaccine (including COVID-19 monoclonal antibody treatments) is administered should also add modifier "25" to identify a medically necessary E&M service furnished on the same day as another service.
New: 5/6/21

21. **Question:** If I am an entity enrolled in the Medicare program, but currently unable to furnish and bill for the administration of vaccines (whether by injection or infusion), what steps do I need to take so that I can administer and bill for COVID-19 vaccines, including the monoclonal antibody treatments?
Answer: If you are an entity that is not currently able to furnish and bill for Part B vaccines based on your Medicare enrollment status, you can follow the vaccine enrollment information for providers found here: https://www.cms.gov/covidvax-provider. Currently enrolled providers and suppliers may also contact their MAC to furnish and bill for these items and services (including COVID-19 monoclonal antibody treatments).

Most providers can currently bill for COVID-19 vaccines without separately enrolling as a mass immunizer. We note that during the PHE for COVID-19, CMS is treating monoclonal antibody products as preventive COVID-19 vaccines, and providing Medicare payment for monoclonal antibody products (when furnished consistent with each product's FDA EUA or approval) for the treatment of COVID-19, in accordance with Section 3713 of the

Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Therefore, entities not currently able to furnish and bill for Part B vaccines based on their current enrollment status (for example, home infusion therapy suppliers) may enroll as mass immunizers to administer COVID-19 monoclonal antibody treatments when furnished in compliance with each product's FDA EUA or approval, as well as applicable state law and their scope of practice.

The same enrollment process for entities wishing to enroll as a COVID-19 vaccine provider will apply for entities wishing to enroll as a provider to administer monoclonal antibody treatments to treat COVID-19.
Updated: 5/6/21

22. **Question**: For beneficiaries dually covered by Medicare and Medicaid, how will monoclonal antibody products be reimbursed?
Answer: For beneficiaries dually eligible for Medicare and Medicaid, Medicare will be the primary payer for COVID-19 monoclonal antibody treatments. Entities that provide monoclonal antibody treatments to dually eligible beneficiaries should first bill Medicare. During the PHE for COVID-19, Medicare covers monoclonal antibody products to treat COVID-19 as Part B preventive vaccines. Therefore, consistent with section 3713 of the CARES Act, there is no beneficiary cost sharing (copayment or deductible) for a monoclonal antibody product and its administration to treat COVID-19 when furnished in compliance with the product's EUA or approval and billed by an appropriately enrolled Medicare provider or supplier. For specific instructions on how to bill the Medicare program for monoclonal antibody treatments, please see previous questions on billing for COVID-19 monoclonal antibody treatments and the monoclonal antibody program instruction here: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf.

For information on coverage and payment for COVID-19 treatments and vaccines (including monoclonal antibody treatments) under the Medicaid program, see the resources listed in the next Q&A.
Updated: 5/6/21

23. **Question:** Where can I find additional materials related to administering and billing for monoclonal antibody treatments for COVID-19, COVID-19 vaccines, or other COVID-19 treatments under Medicare, Medicaid, and CHIP?
Answer: CMS has released many different resources related to monoclonal antibody treatments for COVID-19, COVID-19 vaccines, and other COVID-19 treatments. We note that for Medicare purposes, CMS considers COVID-19 monoclonal antibody infusions to be COVID-19 vaccines and provides Medicare payment for monoclonal antibody products (when furnished consistent with a FDA EUA or approval) for the treatment of COVID-19, in

accordance with Section 3713 of the CARES Act. Please see the list below for further information.

Medicaid and CHIP:

- COVID-19 Frequently Asked Questions: https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf
- COVID-19 Vaccine Toolkit: https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf

Medicare:

- COVID-19 Monoclonal Antibody Treatment Program Instruction: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf
- COVID-19 Provider Toolkits: https://www.cms.gov/covidvax-provider
- Payment rates, billing codes and associated effective dates: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies

Additional Resources:

- COVID-19 Vaccine Toolkits for providers, health plans and issuers, state Medicaid programs, and Children's Health Insurance Programs can be accessed here: https://www.cms.gov/covidvax
- More information and guidance related to COVID-19 can be accessed on CMS' current emergencies page: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

Updated: 5/6/21

24. Question: How do Institutional Providers bill for COVID-19 monoclonal antibody products and their infusion?
Answer: Medicare payments for COVID-19 monoclonal antibody products and their infusion will be made in the same manner as for COVID-19 and other preventive vaccines (e.g., influenza). Institutional Providers shall bill the product codes with Revenue Code 0636 and infusion codes with Revenue Code 0771. Changes to support roster billing of COVID-19 monoclonal antibody products and their infusion in Fiscal Intermediary Shared System (FISS) have been made. Institutional Providers shall report COVID-19 monoclonal antibody products and their infusion using the date of discharge. See link to CMS website for COVID-19 Vaccines and Monoclonal Antibodies at: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

Because COVID-19 monoclonal antibody products are considered preventive vaccines, they are not eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the

Inpatient Prospective Payment System (IPPS).
Updated: 5/6/21

25. **Question:** How do Institutional Providers bill for COVID-19 monoclonal antibody or COVID-19 immunization vaccine products obtained for free?
Answer: When COVID-19 monoclonal antibody or COVID-19 immunization vaccine doses are provided by the government without charge, providers should only bill for the administration. Health care providers should not include the COVID-19 monoclonal antibody codes or COVID-19 immunization vaccine codes on the claim when the product is provided for free. However, CMS recognizes that many provider billing systems require a charge to be submitted, even when a product is provided for free or without charge. In this instance, Institutional Providers should follow the direction provider in the IOM 100-04, Chapter 32, Section 67.2 – Institutional Billing for No Cost Items. For drugs provided at no cost, institutional providers must report the applicable drug HCPCS code and appropriate units with a token charge of less than $1.01 for the item in the covered charge field and mirror this less than $1.01 amount reported in the non-covered charge field. Institutional Providers must report the "No Cost" item as non-covered.
New: 2/19/21

26. **Question:** How do physicians and other clinicians bill for COVID-19 monoclonal antibody products and their infusion?
Answer: Physicians and other clinicians shall bill the infusion codes with HCPCS codes listed at https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies. Changes to support roster billing of COVID-19 monoclonal antibody products and their infusion have been made in both PC-ACE and MCS. Physicians and other clinicians shall report COVID-19 monoclonal antibody products and their infusion with the appropriate diagnosis code.
Updated: 5/6/21

27. **Question:** How do physicians and non-physician practitioners bill for COVID-19 monoclonal antibody or COVID-19 immunization vaccine products obtained for free?
Answer: When COVID-19 monoclonal antibody or COVID-19 vaccine doses are provided by the government or any other entity without charge, physicians and non-physician practitioners should only bill for the administration of the product. Health care providers should not include the COVID-19 monoclonal antibody codes or COVID-19 immunization vaccine codes on the claim when the product is provided for free. However, CMS recognizes that many provider billing systems require a charge to be submitted, even when a product is provided for free or without charge. In this instance, physicians and non-physician practitioners bill the monoclonal antibody or COVID-19 immunization vaccine with a token charge of $0.01 (one penny).

New: 2/19/21

28. **Question:** Will Medicare require an order from a physician or non-physician practitioner for a COVID-19 immunization vaccine, once they are available?
Answer: No, an order will not be required for COVID-19 immunization vaccines. Therefore, a beneficiary could receive the COVID-19 immunization vaccine upon request without a physician's order and without physician supervision.
New: 2/19/21

29. **Question:** Will Medicare require an order from a physician or non-physician practitioner for a COVID-19 monoclonal antibody infusion?
Answer: Yes, an order will be required for COVID-19 monoclonal antibody infusions. Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:
• It was administered on or after the date of the FDA's approval;
• It is reasonable and necessary for the individual patient; and
• All other applicable coverage requirements are met.
New: 2/19/21

30. **Question:** The FDA has expanded the approved indication for the antiviral drug Veklury (remdesivir) and it is now authorized for the treatment of COVID-19 in certain adults and pediatric patients who are not hospitalized in addition to those that are hospitalized. How will CMS pay for remdesivir if it is administered in the outpatient setting?
Answer: At this time, the federal government is not purchasing remdesivir. As such, Medicare will provide payment for the drug and its administration when the product is administered in according with the FDA authorization or approval. To facilitate payment in outpatient settings, CMS created a Healthcare Common Procedure Coding System (HCPCS) code J0248 for Veklury (remdesivir). J0248 represents 1 mg and units should be reported to reflect dosage administered for each patient. Price per 1 mg unit is determined using the payment methodologies for Medicare Part B drugs under section 1847A of the Social Security Act (the Act), which is $5.512 (effective from December 23, 2021 to March 31, 2022) and updated quarterly.

When Veklury (remdesivir) is administered in a hospital outpatient setting, CMS will pay providers separately for the drug under the Hospital Outpatient Prospective Payment System (OPPS) based on payment methodologies for Medicare Part B drugs under section 1847A of the Act. All standard OPPS policies will apply; however, per the interim final rule with request for comments published on November 6, 2020 titled, "Additional Policy and

Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (85 FR 71159 through 71160), because Veklury (remdesivir) is approved by the FDA for treating COVID-19 and not limited to use in the inpatient setting, for the remainder of the COVID-19 Public Health Emergency payment for Veklury (remdesivir) will not be packaged into a Comprehensive-Ambulatory Payment Classification (C-APC) and paid separately when it is furnished with a primary C-APC service. Payment for the administration Veklury (remdesivir) will be determined based on standard OPPS payment methodologies, which are made based on payment amounts set for the applicable CPT code.

When administered incident to a physician's service, payment for Veklury (remdesivir) will be based on payment methodologies for Medicare Part B drugs under section 1847A of the Social Security Act (the Act), and payment for its administration will be based on the physician fee schedule for the applicable CPT code.

For example, a provider administering Veklury (remdesivir) in the outpatient setting would bill J0248 for the product and could use the following CPT code for its administration:

- 96365 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour),
- and if needed use: 96366 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure).

For skilled nursing facility patients that are no longer in a part A stay or for residents of a nursing facility, Medicare policies regarding payment for Veklury (remdesivir) are consistent with policies for other infused drugs.

Questions about coverage of the off-label use of Veklury (remdesivir) should be directed to the Medicare Administrative Contractor (MAC) that processes a provider or supplier's claims. Providers and suppliers can look up the MAC that process the claims for their jurisdiction here: https://www.cms.gov/MAC-info

- For specific payment and coding information for Veklury (remdesivir), see the ASP drug pricing files for October 2021 and January 2022.
- For specific payment and coding information for the administration of Veklury (remdesivir) under the hospital outpatient prospective payment system, see the Addendum A and Addendum B pricing files for January 2022 and subsequent quarterly updates.
- For specific payment information for the administration of Veklury (remdesivir) under the physician fee schedule, see the Physician Fee Schedule Look-up Tool available here.
- For more information regarding payment for drugs under Medicare Part B, see Pub 100-02, Chapter 15 and Pub 100-04, Chapter 17.

- For more information regarding use of Veklury (remdesivir), see FDA press release and the new FDA package insert linked.

  Updated: 2/16/22

31. Question: Who can administer the COVID-19 vaccine to Medicare beneficiaries?
Answer: Individuals who are authorized under applicable state scope of practice and licensure requirements may administer vaccines to Medicare beneficiaries. The list of health care provider types eligible to enroll and bill Medicare for the COVID-19 vaccination is available in the provider toolkit located here: https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots.
Updated: 3/5/21

CC. National Coverage Determinations (NCD)

1. Question: Are all LCD/NCD medical necessity DME criteria waived under CMS-1744-IFC, Section U? Specifically, are the requirements for in person pre-service interactions waived for DME?
Answer: No. While CMS-1744-IFC waived certain coverage criteria and/or in-person encounter requirements (for items other than power mobility devices), the medical record must be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary). We remind physicians, practitioners, and suppliers that, unless there is a specific exception, services and equipment furnished to patients must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.
CMS-1744-IFC finalized that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for other implied face-to-face services, those requirements would not apply during the public health emergency (PHE) for the COVID-19 pandemic. However, some face-to-face encounter requirements for DMEPOS Power Mobility Devices (PMDs) are mandated by statute for program integrity purposes. The IFC does not apply to those statutory requirements.
New: 4/23/20

2. Question: Regarding face-to-face requirements, some drugs require the first few doses to be administered by a healthcare professional before DME coverage begins. Would the infusion nurse/supplier be able to provide first doses at a beneficiary's home as long as the physician is there virtually?
Answer: Physicians (including those practicing in free-standing infusion centers) can furnish physicians' services, including medically necessary injected or infused drugs, in the patient's home. Through flexibility adopted in the March 31st interim final rule, physicians can also furnish services in the patient's home as an incident to their professional services with their

auxiliary personnel, as defined in our regulation at §410.26(a)(1), under direct supervision which is provided using interactive audio-video technology. This allows physicians to leverage additional staff and technology necessary to provide care outside their office setting, for example, with contracted auxiliary personnel, under direct supervision using interactive audio-video technology. For example, physicians may enter into contractual arrangements with a home health agency (defined under section 1861(o) of the Act), a qualified infusion therapy supplier (defined under section 1861(iii)(3)(D) of the Act), or entities that furnish ambulance services in order to utilize their nurses or other clinical staff as auxiliary personnel under leased employment (§410.26(a)(5)). In such instances, Medicare payment for the services furnished directly by physicians, and provided by auxiliary personnel incident to their professional services, would be made to the billing practitioner who would then make the appropriate payment to the contracted entity (for example, the HHA). Medicare payments would be made to the physician under the PFS, and services would not be considered a home health service under the Medicare home health benefit or a service under the home infusion therapy services benefit. Rather, the entity with which the physician contracts would seek payment from the billing practitioner for any auxiliary personnel they provided and would not submit claims to Medicare for such services.

The safety of the patient needs to be considered regarding the setting for patient treatment. Accordingly, the healthcare professional will need to use their clinical judgment when considering virtual services. We recommend that the healthcare provider also take into account the reasonable accommodations of the individual and be inclusive of caregivers in the treatment process. We remind physicians, practitioners and suppliers that services and equipment furnished to patients must be reasonable and necessary. Accordingly, the medical record should be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary).
New: 4/23/20

3. **Question:** With the lifting of certain clinical indications in the IFC, does that allow for home oxygen coverage for Medicare/Medicaid beneficiaries for non-respiratory conditions, such as with cluster headache?
   Answer: No. During the Public Health Emergency, we will not enforce the clinical indications for coverage across respiratory NCDs and LCDs (including articles) to allow for maximum flexibility for practitioners to care for their patients with respiratory conditions. While respiratory devices for acute respiratory conditions are covered as described in Section U of CMS-1744-IFC, these changes do not apply to non-respiratory conditions like cluster headaches.
   New: 4/23/20

4. Are there other NCDs/LCDs whose clinical indications will not be enforced during the COVID-19 PHE?
   Answer: Yes, our April 6, 2020 interim final rule with comment includes, but is not limited to, respiratory, anticoagulation management and infusion pump policies (85 FR 19266). Some NCDs and LCDs are specifically identified in the IFC. In addition to that list, we have identified LCDs for nebulizers and high frequency chest wall oscillation and will continue to update the list in these FAQs if we identify other NCDs or LCDs that fall within the types established in the interim final rule with comment. Questions may be directed to your Medicare Administrative Contractor regarding whether additional NCDs or LCDs should be considered.
   - NCD 240.2 Home Oxygen
   - NCD 240.4 Continuous Positive Airway Pressure for Obstructive Sleep Apnea
   - LCD L33800 Respiratory Assist Devices (ventilators for home use)
   - NCD 240.5 Intrapulmonary Percussive Ventilator
   - LCD L33797 Oxygen and Oxygen Equipment (for home use)
   - NCD 190.11 Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management.
   - NCD 280.14 Infusion Pumps.
   - LCD L33794 External Infusion Pumps.
   - LCD L33785 High frequency chest wall oscillation.
   - LCD L33370 Nebulizers.
   - LCD L33822 Glucose Monitors.
   - LCD L35434 Oximetry services.
   - LCD L33718Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea
   - LCD L33611 Oral Appliances for the Treatment of Obstructive Sleep Apnea
   - LCD L33800 Respiratory Assist Devices
   - LCD L33795 Mechanical In-exsufflation Devices

   Updated: 12/8/20

5. **Question:** Can an exception be made to allow hyperbaric oxygen (HBO) where we can treat, only when medically necessary, COVID-19 patients specifically where Pulmonary Fibrosis or other related conditions are at play?
   Answer: No. The NCD for HBO (20.29) is not one of the types of NCDs under CMS-1744-IFC, Section U. In the Medicare population, HBO is used primarily to treat chronic wounds and not lung disease so it is not included.
   New: 4/23/20

6. **Question:** If an LCD or NCD is not specifically listed in CMS-1744-IFC, Section U, are the clinical indications lifted? For example, would the nebulizer LCD/NCD be included in CMS-1744-IFC, Section U?
   Answer: As long as the LCD or NCD is respiratory, home anticoagulation management, or infusion pump-related, it would fall under CMS-1744-IFC, Section U. The list of covered NCD and LCDs in CMS-1744-IFC, Section U is not all-inclusive. In the example of the nebulizer LCD/NCD, it falls under CMS-1744-IFC, Section U because it is respiratory-related. We remind physicians, practitioners and suppliers that services and equipment furnished to patients must be reasonable and necessary. Accordingly, the medical record should be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary).
   New: 4/23/20

7. **Question:** Can a telehealth service meet the face-to-face requirement for a prosthetic?
   Answer: Perhaps. The regulation at 42 CFR 410.38 recognizes that the face-to-face requirements can be satisfied by using telehealth services for some prosthetic devices. Under the regulations, CMS established a master list of DMEPOS items potentially subject to face-to-face and other requirements that are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Social Security Act. The criteria for this list are specified in 42 CFR 414.234. The Master List serves as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.
   New: 6/2/20

8. **Question:** Can I use telehealth to satisfy the face-to-face requirement in NCDs and LCDs during the COVID-19 public health emergency (PHE)?
   Answer: During the COVID-19 PHE, we will not enforce the face-to-face requirements required through NCDs, LCDs, or articles. To the extent that a provider, supplier, or physician would like to use telehealth services during this period in lieu of a face-to-face visit that would otherwise be specified in an NCD, LCD, or article, they are free to do so. For periods outside of the public health emergency, please consult existing instructions when telehealth services could be used to satisfy NCD and LCD requirements in accordance with the Agency's current telehealth guidance.
   https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index

   Note that certain items of durable medical equipment may have different requirements that are not addressed in NCDs and LCDs but are instead required by statute, regulation, or the DMEPOS Quality Standards (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html). Those requirements are still enforceable during the COVID-19 PHE.

New: 6/2/20

9. **Question:** During the public health emergency (PHE) for the COVID-19 pandemic, does the requirement for a face-to-face examination apply for power mobility devices?
   Answer: Yes. Power mobility devices continue to require face-to-face examination and a written prescription for the item, as mandated by statute and regulation (section 1834(a)(1)(E))(iv) of the Act and 42 C.F.R. §410.38). The face-to-face encounter may be conducted via telehealth.
   New: 6/2/20

10. **Question:** CMS-1744-IFC (April 6, 2020) established that CMS will not enforce certain requirements for face-to-face or in-person encounters for evaluations, assessments, and certifications, that would otherwise apply through NCDs, LCDs, or articles during the PHE. Does this mean that documentation indicating that a beneficiary meets coverage criteria for the DMEPOS is not necessary? What are the requirements for physician or non-physician signatures?
    Answer: No, these requirements are still required during the PHE. We remind physicians, practitioners, and suppliers that services and equipment furnished to patients must be reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Accordingly, the medical record should be sufficient to demonstrate that payment for the services billed is warranted (that is, the services were actually provided, were provided at the level billed, and were medically necessary). Power Mobility Devices (PMDs) require a written order prior to delivery. Other DMEPOS require written orders with a practitioner signature before the claim is submitted for payment (42 CFR 410.38(d)). Practitioners can submit electronic signatures to suppliers as needed.
    New: 6/2/20

11. **Question:** Regarding oxygen patients who are not able to be seen by a physician according to the timeframe typically required by the LCD, may they continue receiving oxygen and is it appropriate for the supplier to submit a bill, since the CMS-1744-IFC (April 6, 2020) waives clinical requirements during the public health emergency?
    Answer: Yes, they may continue to receive oxygen and yes, the supplier may submit a bill. Face-to-face requirements for evaluations, assessments, certifications or other implied face-to-face services as required in NCDs and LCDs do not apply during the PHE for the COVID-19 PHE. The safety of the patient needs to be considered regarding the setting for patient treatment. Accordingly, the healthcare professional will need to use their clinical judgment. We remind physicians, practitioners and suppliers that services and equipment furnished to patients must be reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Accordingly, the medical record should be sufficient to demonstrate that payment for the services billed is warranted (that is, the services were actually provided, were provided at the level billed, and were medically necessary).

New: 6/2/20

12. **Question:** Since in-home assessments for power mobility devices require the supplier to be face-to-face with the beneficiary, can a virtual in-home assessment be performed to meet NCD/LCD coverage criteria and ensure an item is appropriate to the beneficiary's environment?
    Answer: The supplier must ensure that the item furnished is both medically necessary and able to be used in the beneficiary's home environment. If this can be ascertained and documented via virtual means, this is acceptable.
    New: 6/2/20

13. **Question:** The NCD 240.2 home oxygen policy specifies certain health conditions must be met for coverage. Are these conditions for coverage being enforced during the PHE for the COVID-19 PHE?
    Answer: No. As specified in the CMS-1744-IFC (April 6, 2020), clinical indications for certain respiratory policies will not be enforced during the PHE for the COVID-19 PHE, including NCD 240.2 home oxygen. At the conclusion of the PHE for the COVID-19 PHE, we will return to enforcement of these clinical indications for coverage. We remind physicians, practitioners, and suppliers that services and equipment furnished to patients must be reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Accordingly, the medical record should be sufficient to demonstrate that payment for the services billed is warranted (that is, the services were actually provided, were provided at the level billed, and were medically necessary).
    New: 6/2/20

14. **Question:** Does CMS-1744-IFC (April 6, 2020) temporarily waive restrictions around acquiring supplemental O2 and comfort medications for end of life care outside of the hospice setting, in the beneficiary's home?
    Answer: The current NCDs and LCDs that otherwise restrict coverage of home-use of oxygen to certain clinical conditions will not be enforced during the public health emergency for the COVID-19 PHE. This change is intended to allow practitioners flexibility to treat their patients with home-use of oxygen during this emergency. This enforcement discretion will apply only during the PHE for the COVID–19 pandemic. At the conclusion of the PHE for the COVID–19 pandemic, we will return to enforcement of these clinical indications for coverage. CMS-1744-IFC (April 6, 2020) does not prevent enforcement of any policies related to medications related to end of life care whether the services are furnished in a hospice setting or outside of a hospice setting.
    New: 6/2/20

15. **Question:** Are the conditions of coverage and clinical indications waived and/or modified during the PHE for the COVID-19 pandemic for Tumor Treating Fields Therapy (TTFT)?

Answer: The MACs, generally, have authority to make individual coverage determinations which takes the individual clinical and beneficiary circumstances under consideration. We note that the TTFT LCD has flexibility with regard to documenting the 18-hour daily use requirement. The LCD notes an exception to the 18-hour daily use if the treating practitioner documents there is medical need to limit or interrupt treatment.

CMS established through an interim final rule with comment, CMS-1744-IFC (April 6, 2020), that requirements for face-to-face or in-person encounters in LCDs or NCDs do not apply during the COVID-19 PHE, with certain exceptions not applicable to TTFT. In the second interim final rule with comment, CMS-5531-IFC (May 8, 2020), CMS clarified that physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary). While NCD or LCD face-to-face encounter requirements will not be applied during this COVID-19 PHE, there may be other opportunities to document a beneficiary's average at-home use of the device or a medical need to limit or interrupt treatment. There are expanded flexibilities for telehealth and telephonic services to connect with the patient. Further, while DMEPOS orders continue to require a signature, orders can be signed electronically.

Moreover, TTFT is covered for the treatment of newly diagnosed Glioblastoma Multiforme (GBM) when, among other criteria, it is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later. Should the chemotherapy or radiotherapy be delayed due to COVID-19, the 7 weeks would still not begin until after these treatments have been completed.

In the event a patient cannot initiate TTFT within the 7 week period after completion of the above therapies, the MACs, generally, have authority to make individual coverage determinations, which takes the documented individual clinical and beneficiary circumstances under consideration.
New: 6/2/20

16. **Question:** The April 6, 2020 Interim Final Rule with Comment Period (IFC) finalizes on an interim basis that CMS will not enforce the clinical indications for coverage across infusion pump (NCD 280.14) and (LCD L33794) external infusion pump national and local coverage determinations during the Public Health Emergency for the COVID-19 pandemic. Does this mean that all drugs or only certain drugs can be infused at home?
Answer: Only certain drugs can be infused at home. Durable Medical Equipment Medicare Administrative Contractors (DME MACs) may expand coverage for uses of external infusion pumps for drugs other than those listed in the indications in the infusion pump (NCD 280.14) and external infusion pump (LCD L33794) if they make the determination that the

use of the infusion pump itself is appropriate and necessary for administration of the drug in the patient's home by the patient or caregiver, and that the drug itself is reasonable and necessary for the patient's treatment. This flexibility applies only to clinical indications and not to other policy aspects, such as benefit category determinations, of NCDs and LCDs.
New: 9/11/20

17. **Question:** Will ventilator management services be covered if provided via telehealth?
Answer: Ventilator management services codes (94002-94005) were added to the list of telehealth services. Additional information regarding these codes is available here: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
New: 9/11/20

18. **Question:** Do the coverage flexibilities in the April 6, 2020 IFC1 and May 8, 2020 IFC2 pertaining to face-to-face requirements, direct supervision, and the lifting of certain clinical indications in NCDs or LCDs apply to non-covid-19 patients?
Answer: Yes.
New: 9/11/20

19. **Question:** For a beneficiary to be eligible for Continuous Positive Airway Pressure (CPAP), will Medicare require a sleep study to diagnose obstructive sleep apnea (OSA) during the PHE for COVID-19?
Answer: When OSA is suspected in a Medicare beneficiary and treatment is contemplated, a comprehensive sleep evaluation is important, but not required during the PHE for COVID-19. Along with clinical evaluation, in-lab polysomnography (also known as a sleep study) can be used to help diagnose this condition. However, home sleep testing can replace institutional testing for OSA in appropriate patients. As these tests help to prevent the potential harms of misdiagnosis, they remain among the reasonable and necessary criteria required for the identification of OSA and should be performed during the PHE when possible.

    Beneficiaries with OSA using CPAP therapy is considered reasonable and necessary. We will not enforce the clinical indications for NCD for CPAP for OSA (240.4), including the requirements for a sleep study based diagnosis of OSA during the COVID-19 PHE. However, the medical record must be sufficient to support that Continuous Positive Airway Pressure was reasonable and necessary, including information about how such a determination was made in the absence of sleep testing.
    New: 9/11/20
20. **Question:** Can a Nurse Navigator place an order for Lung Cancer Screening with Low Dose Computed Tomography (LDCT) after a phone interaction with the beneficiary for the subsequent LDCT?

Answer: Yes, to the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service, procedure or any portion thereof, we have provided flexibility that on an interim basis that the chief medical officer or equivalent of the facility can authorize another physician specialty or other practitioner type to meet those requirements during the PHE for the COVID-19 pandemic. See 85 Fed. Reg. at 19267 (April 6, 2020).
New: 9/11/20

21. **Question:** Can providers now prescribe a therapeutic continuous glucose monitor to *all* beneficiaries with diabetes [Type I *and* Type II] for the duration of the COVID-19 PHE, irrespective of their level of insulin dependence and the parameters of the existing local coverage determinations (LCDs), so long as documentation supports its being medically appropriate?
Answer: Yes, our May 8, 2020 interim final rule with comment finalized on an interim basis that we will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs (85 FR 27595) during the COVID-19 PHE. We will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have or relating to the demonstrated need for frequent blood glucose testing. This enforcement discretion will only apply during the public health emergency for the COVID-19 pandemic. We remind physicians, practitioners and DME suppliers that services and equipment furnished to patients must be reasonable and necessary. Accordingly, the medical record should be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary).
New: 9/11/20

22. **Question:** Because CMS is not enforcing clinical indications for certain NCDs and LCDs during the COVID-19 PHE, how will practitioners, providers and suppliers know what indications will be covered and what is required for documentation?
Answer: Standard written orders (SWO) and medical record documentation will be critical in demonstrating to MACs that the service furnished was reasonable and necessary. This is the same process that is used when there is an absence of NCDs or LCDs for an item or service. We remind physicians, practitioners and suppliers that services and equipment furnished to patients must be reasonable and necessary. Accordingly, the medical record should be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary). This flexibility applies only to clinical indications and not to other policy aspects, such as benefit category determinations, of NCDs and LCDs.
New: 9/11/20

23. **Question:** During the PHE, face-to-face and in-person encounters that are required or inferred as part of NCDs and LCDs will not apply. How do practitioners, providers and suppliers interpret this flexibility when it comes to NCDs and LCDs that have coverage

criteria based on a patient's clinical data that can only be collected by physically interacting with the patient?
Answer: The flexibility granted to face-to-face and in-person encounters does not confer changes to the clinical indications of coverage for any LCD or NCD unless otherwise specifically indicated. There may be situations in which practitioners may deem a physical encounter necessary to assess and treat beneficiaries or there may be situations in which practitioners may deem telehealth services necessary. We remind physicians, practitioners and suppliers that services and equipment furnished to patients must be reasonable and necessary (to include the documentation of clinical data) and the medical record should be sufficient to support medical necessity of equipment.
New: 9/11/20

DD. Medicare Payment to Facilities Accepting Government Resources

1. **Question:** Can a skilled nursing facility (SNF) or hospital accept Federal, State, or local government resources (e.g., supplies and staffing assistance) to help with the COVID-19 emergency and still bill Medicare?
   Answer: Yes. Although Medicare usually doesn't allow payment for services that are paid for by a governmental entity, there is an exception for services furnished as a means of controlling infectious diseases (see 42 CFR 411.8(b)(4)).
   Updated: 7/15/20

2. **Question:** Does Medicare pay health care providers such as hospices, hospitals, and skilled nursing facilities (SNFs) separately for personal protective equipment and supplies necessary to prevent the spread of infectious disease?
   Answer: Not directly. Medicare payments for health care services include payment for the supplies necessary to appropriately provide the service, including any personal protective equipment and supplies appropriate for the patient's condition and treatment. However, there are not separate payments for those supplies. Additional resources for infection control, such as supplies or staffing assistance, may be made available from other local, state, or federal government agencies.
   Revised: 4/10/20

EE. Oxygen

1. **Question:** Does Medicare cover home use of oxygen for patients diagnosed with COVID-19?
   Answer: The current national and local coverage determinations that otherwise restrict coverage of home-use of oxygen will not be enforced during the public health emergency for the COVID-19 pandemic. This change is intended to allow practitioners flexibility to treat their patients with home-use of oxygen during this emergency. This enforcement discretion will only apply during the PHE for the COVID–19 pandemic. At the conclusion of the PHE for the COVID–19 pandemic, we will return to enforcement of these clinical indications for coverage.

Revised: 4/10/20

FF. Temporary Department of Defense Sites

1. **Question:** Do temporary Department of Defense (DOD) medical treatment sites bill Medicare for emergency inpatient and outpatient hospital services?
   Answer: No, 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 do not bill civilians or the Medicare program for any services rendered.
   New: 4/17/20

GG. Military Treatment Facilities (MTFs)

1. **Question:** Do Department of Defense (DOD) MTFs bill Medicare for emergency inpatient and outpatient hospital services?
   Answer: The Medicare statute generally prohibits payment to Federal providers like DOD hospitals, but there is an exception for emergency inpatient and outpatient hospital services. CMS and DOD have worked closely on this so that a substantial number of DOD hospitals within the United States can meet this exception and bill Medicare for covered emergency hospital services related to COVID-19 treatment (as well as for covered emergency hospital services not related to COVID-19). Regulations concerning payments are set out at 42 C.F.R. Part 424, subpart G.
   New: 4/17/20

HH. Hospice

1. **Question:** Can hospices furnish services using telecommunications technology during the PHE for the COVID-19 pandemic?
   Answer: Yes. Hospices are able to furnish services using telecommunications technology during the PHE when a patient is receiving routine home care. This can include telephone calls (audio only or TTY), two-way audio-video telecommunications technology that allow for real-time interaction between the patient and clinician (e.g., FaceTime, Skype), and remote patient monitoring. It would be up to the clinical judgment of hospice as to whether such technology can meet the patient's/caregiver's/family's needs and the use of technology should be included on the plan of care for the patient and family.
   New: 5/1/20

2. **Question:** Can hospice physicians/hospice nurse practitioners conduct the required face-to-face encounter for re-certifications using telecommunications technology?
   Answer: Hospices are allowed to use 2-way audio-video telecommunications technology that allows for real-time interaction between the patient and the clinician (e.g., FaceTime, Skype) to satisfy the face-to-face encounter requirement, which is required for the third

benefit period (after the patient has typically been receiving hospice for six months) and each subsequent 60-day benefit period thereafter. An explanation of why the clinical findings from the hospice face-to-face encounter support that the patient still has a life expectancy of six months or less is required as part of the recertification narrative. We do not believe that telephone calls (audio only or TTY) would provide the necessary clinical information for a hospice physician to determine whether the patient continues to have a life expectancy of six months or less. As such, telephone calls (audio only or TTY) cannot be used to satisfy the hospice face-to-face encounter requirement.
New: 5/1/20

3. **Question:** Can hospices include services furnished using telecommunications technology on the hospice claim that it submits to Medicare for payment?
Answer: Only in-person visits (with the exception of social work telephone calls) are to be reported on the hospice claim submitted to Medicare for payment. For purpose of service-intensity add-on (SIA) payments, only in-person visits performed by registered nurses and social workers provided during routine home care during the last seven days of life are eligible for these add-on payments. As a reminder, the SIA payments are made above and beyond the routine home care per diem payment amount. On the hospice cost report, hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care during the PHE for the COVID-19 pandemic as "other patient care services" using Worksheet A, cost center line 46, or a subscript of line 46 through 46.19, cost center code 4600 through 4619, and identifying this cost center as "PHE for COVID-19".
New: 5/1/20

4. **Question:** Can hospices complete the initial and comprehensive assessments virtually or over the phone during the PHE for the COVID-19 pandemic?
Answer: Assuming that the patient is receiving routine home care during the initial and comprehensive assessment timeframe, furnishing services using telecommunications technology (e.g., using two-way audio-video telecommunications technology that allows for real-time interaction between the clinician and the patient, like FaceTime or Skype, or using audio-only or TTY telephone calls) would be compliant if such technology can be used to the extent that it is capable of resulting in a full assessment of the patient and caregiver's needs to inform an individualized plan of care. The initial and comprehensive assessment are the foundation of the plan of care, laying out the patient and family needs/goals and outlining the plan for the delivery of these services. An in-person initial and comprehensive assessment is standard practice and crucial to establishing the patient-hospice relationship. During this PHE, we expect in most, but not all, situations that the initial and comprehensive assessment visits would be done in person (especially when assessing skin/wound care; uncontrolled pain/symptoms; effectively teaching patient/caregiver medication administration, etc.). The assessments must identify the physical, psychosocial, emotional,

and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The ultimate goal of these assessments is to fully identifying the needs of the patient and caregivers to establish an individualized patient-centered plan of care.
New: 5/1/20

II. Ambulatory Surgical Centers (ASC)

1. **Question:** If ASCs had participated in the Accelerated and Advance Payment (AAP) program and Hospital without Walls, do Medicare payments made when the entity is operating as a hospital count toward the recoupment?
   Answer: Yes. Under the COVID-19 Accelerated and Advance Payment (CAAP) program, at this time CMS plans to begin recoupment of the payment 120 days after issuance of the AAP. When the recoupment period begins, all Part A and Part B claim payments for the provider or supplier that received the payment will be applied to the AAP until the end of the recoupment period. For providers covered under the CARES Act (acute inpatient hospitals, children's hospitals, certain cancer hospitals, and critical access hospitals), CMS will begin to fully recover their AAP beginning one year from the date these providers received AAP payments. CMS will begin to fully recover AAP for Non-CARES Act providers and all Part B suppliers starting 210 days from the date of payment. A demand letter will be issued for any balance that remains at the end of the recoupment period. Once a demand letter is issued and if the entity is not able to repay the AAP in full due to financial hardship, they may work with their Medicare Administrative Contractor (MAC) to establish an extended repayment schedule (ERS); however, interest will start to accrue on the unpaid balance 31 days after issuance of the demand letter.

   We note that on April 26, 2020, CMS issued a notice that it was suspending Advanced Payments for Part B suppliers and would no longer be accepting applications for this program. CMS also announced that it would be reevaluating new and pending applications for its Accelerated Payment Program. These announcements follow the provision of additional funding for healthcare providers under the Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139 (2020), as well as the initial resources provided by Congress under the CARES Act. These funds are being distributed through HHS's CARES Act Provider Relief Fund, and, unlike funds from the Accelerated and Advance Payment Program, they do not need to be repaid. We encourage providers in need of additional liquidity to apply for funding from the Provider Relief fund at www.hhs.gov/providerrelief
   New: 5/1/20

2. **Question:** If enrolling as a hospital, will the facility be able to bill for services under both Parts A and B?
   Answer: Once the ASC is successfully enrolled as a hospital during the PHE, they will be able

to bill for all facility and professional services within the scope of their licensure and expertise. These facilities should ensure that they are appropriately resourced for the types of procedures they are performing. They would be able to bill for all services that an acute care hospital is able to bill for, including inpatient and outpatient services under both Parts A and B. We remind ASCs that converted their enrollment to a hospital during the PHE that they should be performing services in a manner which is not inconsistent with their state's emergency preparedness or pandemic plan.
New: 11/16/21

3. **Question:** If an ASC enrolls as a hospital and elects to resume its operation as an ASC prior to the end of the PHE, is this resumption of ASC billing privileges effective on the postmarked date of the notification from the ASC, or does the ASC need to receive a form in return from the MAC or the regional office?
   Answer: If the temporarily enrolled hospital decides to revert back to an ASC prior to the end of the PHE period, they must notify their MAC in writing. The notification should include the hospital and ASC's Legal Business Name, Tax Identification Number, National Provider Identifier, Provider Transaction Access Number and the requested deactivation date of the hospital's temporary billing privileges. The ASC's billing privileges will be restored as of the date of postmarking, although a lag may be required to process the notification. The MAC will notify the ASC when their billing privileges have been restored. However, the ASC does not need to wait for this notification from the MAC to resume normal operations.

   Note that the ASC must be in compliance with all applicable ASC federal participation requirements, including the ASC Conditions for Coverage, before billing privileges can be restored.
   New: 5/1/20

4. **Question:** If CMS deactivates the ASC's billing privileges when it enrolls as a hospital, are private payers, who often use the same Medicare PTAN, able to continue to use the ASC PTAN to process reimbursement, even though Medicare has issued a hospital PTAN for the entity?
   Answer: CMS's temporary deactivation of an ASC's PTAN to process payment should have no direct bearing on the ability of private payers to use this number for their own payment processing purposes; however, we cannot speak directly for private payers or to the operations of their payment systems. Facilities should contact payers with whom they have network arrangements or otherwise do business with to verify how conversion to a hospital may impact their ability to receive payment.
   New: 5/1/20

5. **Question:** Is it possible for an ASC to affiliate with multiple hospitals in a market?
   Answer: Assuming for the purposes of this response, provided that the ASC that becomes a hospital is in compliance with COPs to the extent not waived, the ASC can provide inpatient and outpatient hospital services under arrangements with multiple hospitals. An ASC furnishing services under arrangements with a hospital is not eligible to directly bill Medicare for those services, and should seek reimbursement from the hospital for which it is performing services under the terms of the arrangement. Medicare is generally not involved with contractual agreements between private entities, including those associated with services furnished "under arrangements."
   New: 5/1/20

6. **Question:** Do ASCs enrolling as a hospital during the PHE only receive hospital rates for cases they were not previously performing?
   Answer: No. An ASC which chooses to utilize the waivers provided by CMS to convert into a hospital will be a hospital for the duration of the PHE, and will be paid as a hospital for all covered services furnished. Facilities enrolling as a hospital for the duration of the PHE should ensure that they are operating in a manner which is consistent with the state pandemic preparedness plan, and that they satisfy all COPs not waived.
   New: 5/1/20

7. **Question:** Are only inpatient cases at an ASC-become-hospital now billed/paid as hospital under Part A? Will previously-scheduled outpatient procedures scheduled at ASC also be billed as hospital services? Or can this institution bill as a hospital only if a hospital physician performs a treatment or procedure at our ASC-become-hospital?
   Answer:
   - ASCs not temporarily recertifying as hospitals, but that are instead operating under arrangements with a hospital, should seek payment from the hospital, if applicable, under the terms of their contract, which may or may not permit them to continue to provide their own ASC services.
   - ASCs furnishing services as a temporary provider-based department within a hospital are considered part of the hospital and therefore cannot bill independently as an ASC for other services.
   - An ASC which utilizes the waivers provided by CMS to convert to a hospital for the duration of the PHE will be paid as a hospital under the appropriate part of Medicare depending on whether the patient is admitted (i.e., inpatient vs. outpatient) and will be subject to all Medicare payment policies and limitations to the extent not waived (e.g., two midnight rule and MOON).

   New: 5/1/20

8. **Question:** Which claim form do I use when an ASC is temporarily enrolling as a hospital during the COVID-19 Public Health Emergency (PHE)?

Answer: Once the ASC is successfully enrolled as a hospital during the PHE, they will use the 837I electronic transaction/CMS-1450 (UB-04) paper form. Free billing software called PC-ACE is available from your A/B MAC.
New: 2/19/21

9. **Question:** How can I get my remittance advice when an ASC is temporarily enrolling as a hospital during the PHE?
   Answer: Providers are required to obtain Electronic Funds Transfers and Electronic Remittance Advice (ERA). Medicare provides free software to read the ERA and print an equivalent of a Standard Paper Remit (SPR) using the software. Institutional and professional providers can get PC Print and Medicare Remit Easy Print (MREP) respectively from their contractors. These software products enable providers to view and print remittance advice when they are needed, thus eliminating the need to request or await mail delivery of SPRs. The MREP software also enables providers to view, print, and export special reports to Excel and other application programs they may have.
   See the Medicare Claims Processing Manual, (Pub.100-04), Chapters 22 and 24 for further remittance advice information.
   New: 2/19/21

10. **Question:** Which bill type does an ASC that is temporarily enrolling as a hospital use on the billing claim form?
    Answer: ASCs that are enrolling as a hospital during the PHE use Type of Bill 0111 for inpatient service and Type of Bill 0131 for outpatient services. Refer to the Medicare Claims Processing Manual, (Pub.100-04), Chapters 3 and 4 for Inpatient and Part B Hospital Billing.
    New: 2/19/21

11. **Question:** Which Revenue Codes does an ASC that is temporarily enrolling as a hospital use on the billing claim form?
    Answer: ASCs that are enrolling as a hospital during the PHE use revenue codes allowed by the National Uniform Billing Committee. The code list can be obtained by purchasing a "Data Specifications Manual" at NUBC.org.
    New: 2/19/21

12. **Question:** How is an ASC that is temporarily enrolling as a hospital paid by Medicare?
    Answer: Instead of ASC PPS rates, an ASC that is enrolling as a hospital during the PHE is paid under the outpatient prospective payment system (OPPS) for outpatient claims and the inpatient prospective payment system (IPPS) payment system for inpatient claims.
    New: 2/19/21

13. **Question:** After the ASC PTAN has been deactivated, will there be any impact on claims for services that have already been rendered via the ASC?

Answer: Claims for services rendered under the ASC PTAN prior to the date of deactivation will be processed under that PTAN. However, claims with dates of service after the date of deactivation will not be processed under that PTAN.
New: 2/19/21

JJ. Diagnosis Coding under International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

1. **Question**: Where can I find information about coding for the 2019 novel coronavirus disease (COVID-19)?
   Answer: You can find information about coding for the 2019 novel coronavirus disease (COVID-19) from the four cooperating parties for the ICD-10-CM. The four cooperating parties are the American Hospital Association, American Health Information Management Association, Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention/National Center for Health Statistics.
   Centers for Disease Control and Prevention/National Center for Health Statistics:
   - For discharges before April 1, 2020 –
   - https://www.cdc.gov/nchs/data/icd/interim-coding-advice-coronavirus-March-2020-final.pdf
   - For discharges on or after April 1, 2020 -
   - https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf

   Centers for Medicare & Medicaid Services:
   - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software
   - https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM

   A frequently asked questions (FAQ) document, jointly developed and approved by two of the four cooperating parties for ICD-10-CM, the American Hospital Association' Central Office on ICD-10-CM/PCS (the official U.S. Clearinghouse on medical coding) and the American Health Information Management Association is available at:
   - https://www.codingclinicadvisor.com/faqs-icd-10-cm-coding-covid-19
   - https://journal.ahima.org/ahima-and-aha-faq-on-icd-10-cm-coding-for-covid-19/

   New: 5/27/20

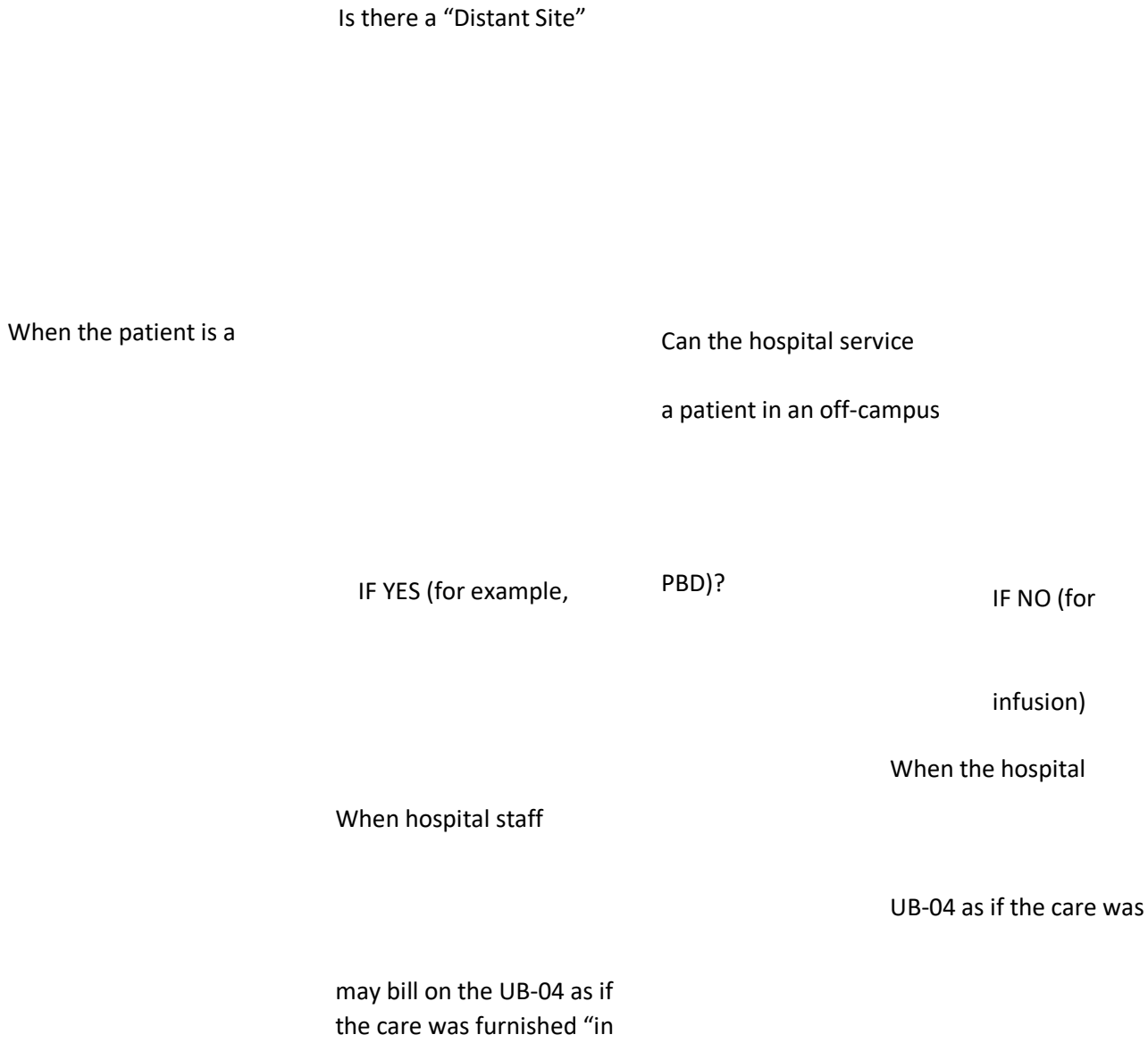
KK. Chronic Care Management Services

1. **Question**: When, how and by whom can beneficiary consent for chronic care management (CCM) services be obtained?
   Answer: Informed consent to receive CCM services must be obtained prior to the start of CCM services. Consent does not have to be obtained at the required initiating visit for CCM that must be performed by the billing practitioner, but it can be obtained at that time. Since the billing practitioner discusses CCM with the beneficiary during the initiating visit, if

consent is separately obtained, it may be obtained under general supervision, and can be verbal as long as it is documented in the medical record and includes notification of the required information. Further, there need not be an employment relationship between the person obtaining the consent and the billing practitioner.
New: 5/27/20

LL. Hospital Billing for Remote Services

1. **Question:** Is there a tool that can help hospitals better understand flexibilities during the COVID-19 PHE when the beneficiary's home is serving as a provider-based department of the hospital (that is, where the hospital ensures the location meets all of the conditions of participation, to the extent not waived, and registers the beneficiary as a hospital outpatient)?
   Answer: The following graphic shows flexibilities during the COVID-19 PHE and can help inform appropriate hospital billing in such situations. Note that a telehealth service would need to be furnished by a physician or other practitioner located at a distant site in order for a hospital to bill for the originating site facility fee. Please see separate graphic and FAQs in this document on billing for therapy via telehealth.



*The hospital should follow billing instructions for using the PO/PN modifiers as applicable.

*For hospital outpatient department services that do not involve a distant site provider, but are furnished in an off-campus PBD, hospitals should bill for furnished services on the UB-04 as though the care was furnished in the hospital (whether the service is furnished in the patient's home or via real-time audio-visual communications). We expect hospitals to properly identify services that can be furnished with telecommunications technology.
New: 7/28/20

2. **Question:** Can hospitals and other institutional providers bill for telehealth services that are furnished by certain practitioners?
Answer: In general, no. While a hospital may bill for certain "remote services" furnished in a provider based department (which may include the patient's home during the COVID-19 PHE), hospitals and other institutional providers are not generally permitted to bill for telehealth services. Telehealth services are professional (that is, physician or practitioner) services furnished using interactive audio and video technology (with certain exceptions in the context of the COVID-19 PHE). The individual physician or practitioner is located at a distant site when furnishing the telehealth service to a beneficiary who is in a different location, the "telehealth originating site." A hospital may serve as the originating site, and can bill for an originating site facility fee for a registered hospital outpatient who is receiving a telehealth service.

   Billing for telehealth services is distinct from billing for hospital services and other institutional services, and in most circumstances occurs using professional claims, not institutional claims that would be submitted by the hospital or other institutional provider.

   We note that prior to the COVID-19 PHE, CAHs that elect CAH Method II billing for professional services bill using the institutional claim format (UB-04). Under the COVID-19 PHE, Method II CAHs, can similarly bill using the institutional claim format for telehealth services furnished by practitioners that can furnish telehealth services as they can outside of the PHE.
   New: 7/28/20

3. **Question:** For services furnished to patients in a provider-based department of the hospital (which may include the patient's home during the COVID-19 PHE), when can a hospital bill for the clinic visit code (G0463, "Hospital outpatient clinic visit") and when can a hospital bill for the originating site facility fee (Q3014)?
Answer: We remind readers that the provider should bill using the HCPCS code that describes the service(s) that were furnished. The following information may help hospitals determine appropriate billing.

- If a distant site practitioner furnishes a telehealth service to a registered hospital outpatient, and hospital staff provide administrative and clinical support, the hospital may bill for the originating site facility fee (Q3014). It would not be appropriate for the hospital to bill HCPCS code G0463 in this situation.
- HCPCS code G0463 describes a clinic visit furnished in the hospital outpatient setting when the practitioner and the patient are both located within the hospital. Typically, the hospital would bill G0463 when a professional is located in the hospital and furnishes an evaluation and management outpatient service to a hospital outpatient who is also in the hospital. If a physician is practicing from a hospital that has registered the patient as a hospital outpatient in the patient's home, which is serving as a provider-based department of the hospital, we consider the physician and patient to be "in the hospital" and usual hospital outpatient billing rules would apply in terms of billing for the service(s) furnished. In this situation, there is no distant site practitioner and no telehealth service being furnished.
  New: 7/28/20

4. **Question:** When a physician is employed by a hospital and typically furnishes services in the hospital, but furnishes services to a registered hospital outpatient from the physician's home during the COVID-19 public health emergency, can the hospital bill G0463 as they usually would for a clinic visit furnished in the hospital outpatient setting?
   Answer: No, as indicated in FAQ #3 above, the hospital would only bill the originating site facility fee (Q3014) when the visit is furnished via telehealth.
   New: 7/28/20

5. **Question:** When there is no Medicare-enrolled professional billing for a telehealth service, can the hospital furnish services remotely?
   Answer: Yes, as explained in the interim final rule published in the Federal Register on May 8, 2020, so long as the hospital conditions of participation are met (to the extent not waived during the COVID-19 PHE), the hospital may register the beneficiary in his/her home so long as the patient's home is serving as a provider-based department of the hospital for the provision of hospital outpatient services. Some services can be furnished remotely using telecommunications technology, such as behavioral health counseling and nutrition counseling. Hospitals should bill for these services on the UB-04 as if the services were furnished in the hospital. Other services, such as a chemotherapy infusion, require hospital staff to physically be in the patient's home. We expect hospitals to properly identify services that can be furnished with telecommunications technology.

   An example list of outpatient therapy, counseling, and educational services that hospital clinical staff can furnish incident to a physician's or qualified NPP's service during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location that functions as a PBD of the hospital when the beneficiary is registered as an outpatient of the

hospital is posted on the CMS website at: https://www.cms.gov/files/zip/covid-ifc-2-list-hospital-outpatient-services.zip.
New: 7/28/20

MM. Outpatient Therapy Services

1. **Question**: Can outpatient therapy services that are furnished via telehealth and separately paid under Part B be reported on an institutional claim (e.g., UB-04) during the COVID-19 PHE?
   Answer: Yes, outpatient therapy services that are furnished via telehealth, and are separately paid and not included as part of a bundled institutional payment, can be reported on institutional claims with the "-95" modifier applied to the service line. This includes:
   • Hospital – 12X or 13X (for hospital outpatient therapy services);
   • Skilled Nursing Facility (SNF) – 22X or 23X (SNFs may, in some circumstances, furnish Part B physical therapy (PT)/occupational therapy (OT)/speech-language pathology (SLP) services to their own long-term residents);
   • Critical Access Hospital (CAH) – 85X (CAHs may separately provide and bill for PT, OT, and SLP services on 85X bill type);
   • Comprehensive Outpatient Rehabilitation Facility (CORF) – 75X (CORFs provide ambulatory outpatient PT, OT, SLP services);
   • Outpatient Rehabilitation Facility (ORF) – 74X (ORFs, also known as rehabilitation agencies, provide ambulatory outpatient PT & SLP as well as OT services); and
   • Home Health Agency (HHA) – 34X (agencies may separately provide and bill for outpatient PT/OT/SLP services to persons in their homes only if such patients are not under a home health plan of care).
   New: 5/27/20

2. **Question:** Can therapy services furnished using telecommunications technology be paid separately in a Medicare Part A skilled nursing facility (SNF) stay?
   Answer: Provision of therapy services using telecommunications technology (consistent with applicable state scope of practice laws) does not change rules regarding SNF consolidated billing or bundling. For example, Medicare payment for therapy services is bundled into the SNF Prospective Payment System (PPS) rate during a SNF covered Part A stay, regardless of whether or not they are furnished using telecommunications technology. Therapy services furnished to a SNF resident, whether in person or as telehealth services, during a non-covered SNF stay (Part A benefits exhausted, SNF level of care requirement not met, etc.) must be billed to Part B by the SNF itself using bill type 22X, regardless of whether or not they are furnished using telecommunications technology.
   New: 5/27/20

3. **Question:** Can outpatient therapy services be furnished and paid separately for patients

receiving Medicare home health services?

Answer: No. For patients under a home health plan of care, payment for therapy services (unless provided by physicians/non-physician practitioners) is included or bundled into Medicare's payment to the HHA, and those services must be billed by the HHA under the HHA consolidated billing rules. Patients should first be assessed for whether they are eligible to receive therapy services under the home health benefit prior to initiating outpatient therapy services. Receiving therapy services under the home health benefit may be in the best interest of the patient as there is no applicable coinsurance, copay, or deductible for such services (with the exception of negative pressure wound therapy using a disposable device), and the patient may also have a need for skilled nursing services, home health aide services, or medical social services under the home health benefit. However, if the patient is not eligible for home health care, including when it is not possible to provide in-person therapy services in the patient's home (i.e., the patient is not under a home health plan of care), then outpatient therapy furnished via telehealth under Part B could be an appropriate alternative and separately billed, assuming all applicable requirements are otherwise met.

New: 5/27/20

4. **Question:** Is there a graphic that can show me how to bill for outpatient therapy services furnished via telehealth during the COVID-19 Public Health Emergency?
Answer: The below graphic demonstrates the options available to therapists who furnish physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) services via telehealth or under Hospital Without Walls flexibilities.

*The hospital cannot also bill for the originating site facility fee.
New: 7/28/20

2. **Question:** How do hospitals bill for outpatient therapy services furnished by employed or contracted therapists using telecommunications technology on the UB-04 claim form during the COVID-19 PHE?
   Answer: There are two options available to hospitals and their therapists.
   1) A hospital could choose to bill for services furnished by employed/contracted PTs, OTs, or SLPs through telehealth, meaning that they would identify furnished services on the telehealth list (https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes), they would bill these services on a UB-04 with a "-95" modifier on each line for which the service was delivered via telehealth. No POS code is required (and there is no location for it on the UB-04).
   2) A hospital could, instead, use the flexibilities available under the Hospital Without Walls initiative. The hospital would register the patient as a hospital outpatient, where the patient's home acts as a provider-based department of the hospital. The hospital's employed/contracted PT, OT, SLP would furnish the therapy care that the hospital believed could be furnished safely and effectively through telecommunications technology. The hospital is not limited to services included on the telehealth list (since these would not be considered telehealth services), but must ensure the care can be fully furnished remotely using telecommunications technology. The hospital would bill as if the therapy had been furnished in the hospital and the applicable PO/PN modifier would apply for the patient's home since it would be serving as an off-campus department of the hospital.

      The option to bill for telehealth services, along with the -95 modifier, furnished by employed/contracted PTs, OTs, and SLPs using applicable audio-visual telecommunications technology applies to the following types of hospitals and institutions:
      • Hospital – 12X or 13X (for hospital outpatient therapy services);
      • Skilled Nursing Facility (SNF) – 22X or 23X (SNFs may, in some circumstances, furnish Part B PT/ OT/ SLP services to their own long-term residents);
      • Critical Access Hospital (CAH) – 85X (CAHs may separately provide and bill for PT, OT, and SLP services on 85X bill type);
      • Comprehensive Outpatient Rehabilitation Facility (CORF) – 75X (CORFs provide ambulatory outpatient PT, OT, SLP services);
      • Outpatient Rehabilitation Facility (ORF) – 74X (ORFs, also known as rehabilitation agencies, provide ambulatory outpatient PT and SLP, as well as OT services); and
      • Home Health Agency (HHA) – 34X (agencies may separately provide and bill for outpatient PT/OT/SLP services to persons in their homes only if such patients are not

under a home health plan of care).
New: 7/28/20

5. **Question:** In the scenario in which the hospital chooses to bill for telehealth services of an employed/contracted PT, OT, or SLP using a -95 modifier on each applicable service line on a UB-04 for a registered outpatient, can the hospital also bill for the originating site facility fee (Q3104)?
   Answer: No. In this scenario, the hospital must bill on a UB-04 for all PT, OT, and SLP services provided to their outpatients, even when those services are furnished by private practice therapists under arrangement with the hospital, due to provider billing rules and restrictions on where private practice therapists are paid—their offices and patient's homes. In these cases, the hospital cannot bill for the originating site facility fee in addition to the service(s) furnished via telehealth.
   New: 7/28/20

6. **Question:** Does the revised definition of direct supervision that includes virtual presence as defined at 42 CFR 410.32(b)(3)(ii) apply to physical therapists (PTs) and occupational therapists (OTs) in Private Practice who are required to provide direct supervision of their therapy assistants – physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) – when they furnish services?
   Answer: The revised definition of direct supervision at 42 CFR 410.32(b)(3)(ii) allows virtual presence of the supervising professional through the use of interactive telecommunications technology for the duration of the Public Health Emergency (PHE). PTs and OTs in private practice must directly supervise their PTAs and OTAs, respectively, and may do so through their virtual presence whether they are providing supervision of PTAs/OTAs in the office, in the beneficiary's home, or when therapy assistants are furnishing therapy services via telehealth. As direct supervision requires the PT's/OT's immediate availability, but not their constant presence in the room during the service, the PT/OT does not need to be in contact 100% of the time, but they need to be ready to provide the virtual presence whenever it's needed.
   New: 10/6/21

NN. Durable Medical Equipment Interim Pricing in the CARES Act

1. **Question:** Are there any changes to durable medical equipment (DME) fee schedule amounts?
   Answer: Yes. Section 1834(a)(1)(F) of the Social Security Act requires CMS to use pricing information from the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) to adjust the fee schedule amounts for certain DME, and enteral nutrients, supplies, and equipment in areas of the country where the CBP has not previously been implemented. Areas of the country where the CBP has not previously been implemented are called non-competitive bidding areas (non-CBAs). The

methodology that CMS uses to adjust the fee schedule amounts based on information from the CBP is set forth at 42 C.F.R. 414.210(g). Section 3712 of the CARES Act revises the fee schedule adjustment methodology at 42 CFR 414.210(g)(9)(iv) for certain items and services furnished in non-rural and contiguous non-CBAs through the duration of the public health emergency period described in section 1135(g)(1)(B) of the Social Security Act.
New: 6/19/20

2. **Question:** What areas are affected by section 3712 of the CARES Act?
   Answer: Section 3712 of the CARES Act addresses fee schedule amounts for items furnished in non-CBAs that CMS considers rural or non-contiguous. Section 3712 also addresses fee schedule amounts for items furnished in non-CBAs that are non-rural areas within the contiguous U.S. (i.e., non-rural contiguous non-CBA areas). A rural area is defined in 42 CFR 414.202 as a geographic area represented by a postal ZIP code if at least 50 percent of the total geographic area of the area included in the ZIP code is estimated to be outside any metropolitan area (MSA), or a geographic area represented by a postal ZIP code that is a low population density area excluded from a CBA. Non-contiguous areas refer to areas outside the contiguous U.S., such as Alaska, Puerto Rico, and Hawaii. During the two-year gap in the CBP, the fee schedule amounts paid for DME items and services furnished in the former CBAs are based on the single payment amounts paid in 2018 under the CBP increased by annual inflation update factors for 2019 and 2020. The fee schedule amounts paid in the former CBAs are not affected by section 3712 of the CARES Act.
   New: 6/19/20

3. **Question:** How has CMS been paying for DME in the non-CBAs prior to the recent payment changes?
   Answer: CMS has been paying different fee schedule amounts for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs, depending on where the item or service is furnished: 1) rural areas and non-contiguous areas, or 2) non-rural areas within the contiguous U.S. The fee schedule amounts for non-rural contiguous non-CBAs are adjusted based on 100 percent of the average payment amounts under the CBP while the fee schedule amounts for rural and non-contiguous non-CBAs are adjusted based on a blend of 50 percent of the adjusted fee schedule amounts (adjusted based on information from the CBP) and 50 percent of the higher historic, unadjusted fee schedule amounts. CMS started adjusting the fee schedule amounts paid in non-CBAs based on information from competitive bidding information in 2016.
   New: 6/19/20

4. **Question:** What does Section 3712 of the CARES Act change?
   Answer: Section 3712 of the CARES Act continues this bifurcation in fee schedule amounts between non-CBAs that are rural or non-contiguous, and non-rural contiguous non-CBAs. However, section 3712(b) increases the fee schedule amounts CMS pays for certain DME

and enteral nutrition items and services furnished in non-rural contiguous non-CBAs. In accordance with section 3712(b) of the CARES Act, fee schedule amounts for DME items and services furnished non-rural and contiguous non-CBAs are adjusted based on a blend of 75 percent of the adjusted fee schedule amounts and 25 percent of the higher historic, unadjusted fee schedule amounts from March 6, 2020 through the duration of the public health emergency period. Section 3712(a) continues the 50/50 blend in rural and non-contiguous non-CBAs as planned through December 31, 2020, or through the duration of the public health emergency period, whichever is longer.
New: 6/19/20

5. **Question:** How much does section 3712(b) of the CARES Act raise fee schedule amounts, on average, for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs that are non-rural or contiguous?
   Answer: It is estimated that section 3712(b) of the CARES Act raises fee schedule amounts for these items and services furnished in non-rural and contiguous non-CBAs by 33% on average.
   New: 6/19/20

6. **Question:** When will the changes in section 3712 of the CARES Act take effect, and how long will they last?
   Answer: As discussed, Section 3712(b) of the CARES Act increases the fee schedule amounts for certain DME items and enteral nutrients, supplies and equipment services furnished in non-rural contiguous non-CBAs effective on March 6, 2020, and these higher fee schedule amounts will be effective through the remainder of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b-5(g)(1)(B)). Should the public health emergency period expire on or before December 31, 2020, the fee schedule amounts for DME items and services furnished in non-rural contiguous non-CBAs will again be based on 100 percent of the adjusted payment amounts. The current fee schedule adjustments for items and services furnished in non-CBAs that are rural or non-contiguous will continue as planned through December 31, 2020, or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act, if longer. More information on the implementation of these changes is available on the CMS DME Center website here: https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.
   New: 6/19/20

OO. Medical Education

1. **Question:** What is a teaching hospital?
   Answer: Under 42 CFR § 415.152, a teaching hospital is defined as a hospital engaged in an approved Graduate Medical Education (GME) residency program in medicine, osteopathy, dentistry, or podiatry.

New: 6/19/20

2. **Question:** Where can I find general information on CMS policies regarding Medicare Graduate Medical Education (GME) Payment Amounts?
Answer: In general, under existing policies for Direct Graduate Medical Education (DGME) (see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME and 42 CFR §§ 413.75 – 413.83), the calculation of DGME payment amounts is affected by the hospital's number of full-time equivalent (FTE) residents (up to the hospital's "cap" in the case of allopathic and osteopathic residents), the hospital's per resident amount (PRA), and the hospital's Medicare utilization.

   Additionally, under existing policies for Indirect Medical Education (IME) (see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Indirect-Medical-Education-IME and 42 CFR § 412.105), CMS makes an additional payment for each Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to non-teaching hospitals.

   The additional payment is based on the IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds, which is represented as r, and a multiplier, which is represented as c, in the following equation: $c \times [(1 + r)^{0.405} - 1]$. The multiplier c is set by Congress, and its current value is 1.35. Thus, the amount of IME payment that a hospital receives is dependent upon the number of residents the hospital trains, the number of available beds, and the current level of the IME multiplier.
   New: 6/19/20

3. **Question:** What changes did CMS announce regarding IME and DGME payments?
Answer: CMS recently announced that for the duration of the COVID-19 PHE, a teaching hospital that sends residents to other hospitals will be able to continue to claim those residents in the teaching hospital's IME and DGME resident FTE counts in accordance with 42 CFR § 413.78(i) (see 85 FR 27550, 27623). Moreover, the presence of residents in non-teaching hospitals will not trigger establishment of IME and/or DGME FTE resident caps at those non-teaching hospitals. In addition, specifically for DGME, the presence of residents in non-teaching hospitals will not trigger establishment of PRAs at those non-teaching hospitals. This measure is intended to ensure that teaching hospitals are able to send residents, on an emergency basis to hospitals where they are most needed to treat patients with or without COVID-19. We recognize these actions are a significant departure from prior policy and these actions are being taken only in light of the unprecedented nature of the COVID-19 PHE.
   New: 6/19/20

4. **Question:** What additional changes did CMS announce regarding IME payments?
   Answer: To hold teaching hospitals harmless from a reduction in IME payments caused by a temporary increase in the number of available hospital beds to accommodate an expected influx of COVID-19 patients, CMS recently announced that beds temporarily added during the PHE for COVID-19 will be excluded from the calculations to determine IME payment amounts in accordance with 42 CFR § 412.105(d)(1).
   New: 6/19/20

5. **Question:** Will my Inpatient Rehabilitation Facility (IRF) or Inpatient Psychiatric Facility (IPF) teaching status adjustment payments be impacted because we have more patients due to COVID-19 or move patients around because of COVID-19?
   Answer: No, CMS is holding IPF and IRF teaching status adjustment payments harmless for the duration of the PHE. This means the teaching status adjustment amounts for the IRF and IPF hospitals and units of hospitals will be the same during the COVID-19 PHE as they were on the day before the PHE was declared, in order to hold their teaching status adjustment payments harmless during the pandemic.
   New: 6/19/20

PP. Applicability Dates of Provisions in Second IFC

1. **Question:** What are the applicability dates for the provisions in the second IFC?
   Answer: Most policies in these regulations are applicable beginning on January 27, 2020 or March 1, 2020, as described in the preamble of the IFC, unless otherwise noted. All provisions with an applicability date other than January 27, 2020 or March 1, 2020 are noted in the table below.

Provision	Applicability Date
Medicare Shared Savings Program – Expansion of Codes used in Beneficiary Assignment	We are revising § 425.400 to expand the definition of primary care services used in the Shared Savings Program beneficiary assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID-19 pandemic, as defined in § 400.200, which includes any subsequent renewals.
Modification to Medicare Rules and Medicaid Concerning Certification and Provision of Home Health Services	We are revising §§ 409.41 through 409.48; 424.22; 424.507(b)(1); § 440.70(a)(2) and (3) and § 440.70(b)(1), (2) and (4); and several sections of 42 CFR part 484 to include

	physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services. These changes are permanent, and applicable to services provided on or after March 1, 2020.
Flexibility for Medicaid Laboratory Services	We are revising § 440.30 to provide states with flexibility to provide Medicaid coverage for certain laboratory tests and X-ray services that may not meet certain requirements in § 440.30 (a) or (b) (such as the requirement that tests be furnished in an office or similar facility). This flexibility is retroactive to March 1, 2020, during the period of the COVID-19 PHE and for any subsequent periods of active surveillance. The flexibility also applies to future PHEs resulting from outbreaks of communicable disease and subsequent periods of active surveillance.
Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19	We are revising § 483.80 to establish explicit reporting requirements for long-term care facilities to report information related to COVID-19 cases among facility residents and staff. These reporting requirements are applicable on the effective date of this IFC.
Separate Billing and Segregation of Funds for Abortion Services	We are delaying by 60 days the date when individual market qualified health plan (QHP) issuers must be in compliance with the separate billing policy for non-Hyde abortion services. Under this 60-day delay, QHP issuers must comply with the separate billing policy beginning on or before the QHP issuer's first billing cycle following August 26, 2020.
DME Interim Pricing in the CARES Act	We are revising § 414.210 to provide increased fee schedule amounts in certain areas starting on March 6, 2020, and for the duration of the PHE for the COVID-19 pandemic.

Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria - Completion of QCDR Measure Testing - Collection of Data on QCDR Measures	For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of the completion of QCDR measure testing policy by 1 year. Specifically, we are amending § 414.1400(b)(3)(v)(C) to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. This change is applicable on the effective date of this IFC. For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of the collection of data on QCDR measures policy by one year. Specifically, we are amending § 414.1400(b)(3)(v)(D) to state that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. This change is applicable on the effective date of this IFC.
Hospital Value-Based Purchasing Program	We are revising the extraordinary circumstances exception policy to allow CMS to grant an exception to hospitals located in an entire region or locale without a request and we are codifying the updated policy at § 412.165(c). This change is permanent, and is applicable beginning on the effective date of this IFC.
IRF Quality Reporting Program	We are revising the compliance date for the IRF Quality Reporting Program to October 1st of the year that is at least one full fiscal year after the end of the PHE. This change is applicable on the effective date of this IFC.
LTCH Quality Reporting Program	We are revising the compliance date for the LTCH Quality Reporting Program to October

	1st of the year that is at least one full fiscal year after the end of the PHE. This change is applicable on the effective date of this IFC.
HH Quality Reporting Program	We are revising the compliance date for the HH Quality Reporting Program to January 1st of the year that is at least one full calendar year after the end of the PHE. This change is applicable on the effective date of this IFC.
SNF Quality Reporting Program	We are revising the compliance date for the SNF Quality Reporting Program to October 1st of the year that is at least two full fiscal years after the end of the PHE. This change is applicable on the effective date of this IFC.

New: 6/19/20

QQ. Indian Health Service (IHS) Hospitals

1. **Question:** During the COVID-19 Public Health Emergency (PHE), does Medicare pay Indian Health Service (IHS) hospitals an all-inclusive outpatient per visit rate (AIR) for COVID-19 specimen collection and laboratory testing provided by the HOPD staff when the beneficiary did not interact with a physician or non-physician practitioner (NPP)?
   Answer: Yes. An IHS outpatient clinic visit for COVID-19 specimen collection and/or laboratory testing will qualify as a billable encounter for purposes of the AIR, even if the patient does not have a face-to-face encounter with a physician or NPP. This is effective for COVID-19 specimen collection and/or diagnostic testing provided on or after March 1, 2020, and for the duration of the COVID-19 PHE.
   New: 12/1/20

2. **Question:** How can IHS hospitals bill for COVID-19 specimen collection and COVID-19 laboratory testing provided by HOPD staff?
   Answer: During the PHE, IHS hospitals shall use type of Bill (TOB) 013x claims to report the charges for COVID-19 specimen collection (using HCPCS code C9803) and/or diagnostic laboratory testing services under revenue code 0510 (clinic visit). Providers shall include the "CS" modifier, as applicable, to ensure beneficiary cost-sharing is not applied. While we assume that most IHS hospitals are providing both COVID-19 specimen collection and diagnostic testing, IHS hospitals may provide only specimen collection or only diagnostic testing as appropriate and bill for the AIR.
   New: 12/1/20

3. **Question:** Can the IHS hospital receive additional payment for COVID-19 specimen collection and/or laboratory testing provided on the same day as an otherwise billable

encounter?
Answer: No. When specimen collection and/or laboratory testing are provided on the same date as other covered outpatient services, the outpatient services should be billed only once (i.e., all-inclusive) and are paid under a single outpatient AIR.
New: 12/1/20

4. **Question:** Can an IHS hospital bill the outpatient AIR for purchased COVID-19 laboratory services?
Answer: Yes. If the IHS hospital purchases COVID-19 diagnostic services from another entity, that entity bills the hospital; the hospital bills Medicare and is paid based on the AIR. This policy applies to COVID-19 diagnostic testing services that, for example, the IHS hospital performs under arrangement with a reference laboratory. In this scenario, the reference lab cannot also bill Medicare directly.
New: 12/1/20

5. **Question:** Can the IHS hospital bill for COVID-19 laboratory testing on a 13X TOB under the outpatient AIR if Medicare paid for these services on a different type of bill?
Answer: No. If the IHS hospital or another entity submitted a different type of bill and received Medicare payment for COVID-19 laboratory testing that can be billed on a 13X and paid based on the AIR, the IHS hospital (and the other entity, if applicable) may work with the MAC to cancel the previous claim before submitting a claim for COVID-19 laboratory testing on a 13X TOB.
New: 12/1/20

6. **Question:** Can Indian Health Service (IHS) and Tribal hospitals be reimbursed at the Medicare outpatient All-Inclusive rate (AIR) for services furnished remotely by hospital staff to Medicare beneficiaries during the PHE?
Answer: Yes, existing COVID-19 Medicare waivers in effect during the PHE apply to IHS and Tribal hospitals and allow them to bill for hospital outpatient services furnished remotely to Medicare beneficiaries. This flexibility applies when the clinical staff are in person, at the beneficiary's home, or when telecommunications technology is used to connect the beneficiary and hospital staff. In these circumstances, assuming all other requirements are met, IHS and Tribal hospitals can bill and be paid as if the services were provided face-to-face.

   Please refer to the section titled "LL. Hospital Billing for Remote Services" in these FAQs for more information about these flexibilities.
   New: 7/2/20