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Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

OVERVIEW

On March 30th, the Centers for Medicare and Medicaid Services (CMS) issued a wide-ranging set of temporary regulatory waivers offering new flexibilities in response to the COVID-19 public health emergency (PHE). The waivers pertain mostly to Medicare rules, with some Medicaid components. They went into effect nationwide immediately and will last for the duration of the emergency. The Interim Final Rule is available here. Major provisions are outlined below.

MEDICARE PROGRAM CHANGES

Merit-Based Incentive Payment System (MIPS)

CMS has determined that the MIPS automatic extreme and uncontrollable circumstances policy will apply to MIPS eligible clinicians who fail to submit their MIPS data by the extended timeline. Under this policy, MIPS eligible clinicians who are not participants in Alternative Payment Models and who do not submit any MIPS data will have all performance categories reweighted to 0%, resulting in a score equal to the performance threshold, and a neutral MIPS payment adjustment. If a MIPS eligible clinician submits data on two or more MIPS performance categories, they will be scored and receive a 2021 MIPS payment adjustment based on their final score.

CMS is applying the MIPS automatic extreme and uncontrollable circumstances policy to MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year. CMS has extended the deadline to submit an application for reweighting the quality, cost, and improvement activities performance categories based on extreme and uncontrollable circumstances and the Promoting Interoperability performance category based on extreme and uncontrollable circumstances from December 31, 2019 to April 30, 2020, or a later date that CMS may specify. CMS is also modifying existing policy for the 2019 performance period/2021 MIPS payment year so that if a MIPS eligible clinician, group, or virtual group submits an application for reweighting based on the PHE for the COVID-19 pandemic by the extended deadline, any MIPS data they have submitted or will submit would not effectively void their application. Finally, CMS is adding one new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period in response to the PHE.

Part C And Part D Quality Rating Systems

CMS is modifying the calculation of the 2021 and 2022 Part C and D Star Ratings to address the expected disruption to data collection posed by the PHE for the COVID-19 pandemic. Specifically, CMS will:

- No longer require MA plans to collect and submit HEDIS and CAHPS data for 2021 Star Ratings. Plans
 may submit any data collected for internal quality improvement purposes. In lieu of current data, CMS
 will replace the 2021 Star Ratings measures normally calculated based on 2019 HEDIS data and 2020
 CAHPS data with earlier values from the 2020 Star Ratings;
- Modify rules for any other measure that has a systematic data quality issue due to the COVID-19 outbreak to replace it with the measure-level Star Ratings and scores from the 2020 Star Ratings;
- Use the final 2020 Star Ratings for the 2021 score in the event that CMS' functions become focused on only continued performance of essential Agency functions and it cannot calculate the 2021 Star Ratings;



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- Replace measures calculated based on Health Outcome Survey (HOS) data collections with earlier values for the 2022 Star Ratings in the event that CMS is unable to complete HOS data collection in 2020;
- Remove guardrails for the 2022 Star Ratings to allow a greater than 5 percentage point change; and
- Expand the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings.

Advance Payments

CMS is revising the definition of advance payment to suppliers furnishing items or services under Part B to state that the conditional partial payment will be made by the "contractor," as opposed to the carrier. CMS is also waiving conditions that determine when a payment can be made, adding a paragraph to specifically address emergency situations in which it will be able to make advance payments. CMS is increasing anticipated payments for claims based upon the historical assigned claims payment data from 80% to 100%. Suppliers in bankruptcy would not be eligible to receive advance payments.

Innovation Center Models

CMS is making the following changes to Innovation Center Models:

- Medicare Diabetes Prevention Program (MDPP) The IFR permits certain beneficiaries to obtain the set of MDPP services more than once per lifetime, increases the number of virtual make-up sessions, and allows certain MDPP suppliers to deliver virtual MDPP sessions on a temporary basis.
- Comprehensive Care for Joint Replacement (CJR) Model CMS is extending CJR performance year 5 by three months through March 31st, 2021. CMS is also broadening the extreme and uncontrollable circumstances policy by applying certain financial safeguards to participant hospitals that have a CCN primary address that is located in an emergency area for episodes that overlap with the emergency period.
- Other Alternative Payment Models (APMs) CMS recognizes that requirements of other APMs may no longer be appropriate and additional actions may be necessary in a future IFR.

TELEHEALTH

Payment For Medicare Telehealth Services

On March 17th, 2020, CMS announced the expansion of telehealth services on an emergency basis pursuant to waiver authority added by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. Medicare now pays for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's home. If beneficiaries are located in places that are not identified as permissible originating sites, CMS will forego paying the originating site facility fee and will instead only pay the non-facility rate.

CMS is instructing physicians and practitioners who bill for Medicare telehealth services to report the place of service code that would have been reported had the service been furnished in person, and use the CPT telehealth modifier 95. CMS will make payments at the same rate it would have paid if the services were furnished in person.



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Modalities, Cost-Sharing, And Patient Relationships

For the duration of the PHE, CMS is expanding the scope of telehealth technology to include a wider range of interactive telecommunications systems – multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. The HHS Office for Civil Rights is exercising enforcement discretion and waiving penalties for HIPAA violations against health care providers that use everyday communications technologies, such as FaceTime or Skype, for telehealth services.

Physicians and other practitioners will not be subject to administrative sanctions for reducing or waiving any costsharing obligations Federal health care program beneficiaries may owe for telehealth services, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring.

In the CY 2019 Physician Fee Schedule (PFS) final rule, CMS finalized separate payment for a number of services that could be provided via telecommunications. In this rule, CMS is establishing that services affiliated with HCPCS codes G2010 and G2012 can be provided to both new and established patients. Consent to receive these services can be documented by auxiliary staff under general supervision both annually and at the same time that a service is furnished. CMS is also exercising enforcement discretion regarding established patients for CPT codes 99421, 99422 and 99423, and HCPCS codes G2061, G2062, and G2063. Finally, CMS is clarifying that G2016-G2063 may be delivered by licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, or speech language pathologists, who could utilize virtual check-ins and remote evaluations instead of other, in-person services. CMS notes that this is not an exhaustive list and that it is seeking input on other kinds of practitioners who may furnish these kinds of services during the COVID-19 PHE.

New Medicare Telehealth Services

During the PHE, CMS is adding the following services to the Medicare telehealth list on a Category 2 basis, with dates of service beginning March 1st, 2020 through the end of the declared PHE, including any subsequent renewals:

- 5 Emergency Department Visits CPT codes;
- 10 Initial and Subsequent Observation, and Observation Discharge Day Management CPT codes;
- 5 Initial hospital care and hospital discharge day management CPT codes;
- 5 Initial nursing facility visits and nursing facility discharge day management CPT codes;
- 2 Critical Care Services CPT codes;
- 6 Domiciliary, Rest Home, or Custodial Care services CPT codes;
- 9 Home Visits CPT codes;
- 7 Inpatient Neonatal and Pediatric Critical Care CPT codes;
- 4 Initial and Continuing Intensive Care Services CPT codes;
- 1 Care Planning for Patients with Cognitive Impairment CPT code;
- 1 Group Psychotherapy CPT code;
- 4 End-Stage Renal Disease (ESRD) Services CPT codes;
- 8 Psychological and Neuropsychological Testing CPT codes;
- 21 Physical Therapy, Occupational Therapy, and Speech-Language Pathology CPT codes; and
- 1 Radiation Treatment Management Services CPT code.

The complete list of telehealth services payable under the Medicare Physician Fee Schedule can be downloaded here.



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Use of Telephone for Evaluation And Management (E/M) Services

CMS is allowing prolonged, audio-only communication between practitioners and patients when Medicare telehealth services are not available, as clinically appropriate. In that regard, CMS is finalizing a separate payment for CPT codes 99441-99443 and CPT codes 98966-98968. To facilitate billing of these services by therapists, CMS is designating CPT codes 98966-98968 as CTBS "sometimes therapy" services that would require the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services.

CMS is specifying that telehealth office/outpatient E/M visits can be provided to any patient in their home regardless of the diagnosis or medical condition. E/M code level selection for these services can be based on MDM or time, with time defined as all of the time associated with the E/M on the day of the encounter. CMS is also removing requirements regarding documentation of history and/or physical exam in the medical record.

Frequency Limitations - Inpatient And Nursing Facility Settings

CMS is removing the frequency restrictions for each of the following listed codes for subsequent inpatient visits and subsequent nursing facility visits provided via Medicare telehealth for the duration of the PHE for the COVID-19 pandemic:

- Subsequent Inpatient Visits: CPT codes 99231-99233
- Subsequent Nursing Facility Visits: CPT codes 99307-99310
- Critical Care Consultation Services: HCPCS codes G0508 and G0509

CMS is also removing the restriction that critical care consultation codes may only be provided to a Medicare beneficiary once per day.

Monthly ESRD Capitation Payments

Individuals determined to have ESRD and who are receiving home dialysis normally must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months. Due to the conditions presented by the PHE, CMS is exercising enforcement discretion, and will not conduct review to consider whether those visits were conducted face-to-face, without the use of telehealth. In general, CMS is allowing the required clinical examination, or "hands on" visits, for ESRD Monthly Capitation Payments to be furnished as a Medicare telehealth service during the PHE for the COVID-19 pandemic.

Home Health Benefit

CMS is allowing Home Health Agencies (HHAs) to provide more services to beneficiaries using telehealth within the 30-day episode of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care. CMS does not expect that services furnished at a patient's home incident to a physician service will usually occur during the same period as a home health episode of care, and has clarified 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. CMS will monitor claims that practitioners are billing under arrangement to ensure appropriate services are being billed by the practitioner and not being inappropriately unbundled from payments under the home health prospective payment system (HH PPS).



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Hospice Benefit

CMS is allowing hospice providers to provide services to a Medicare patient receiving routine home care through telehealth, if it is feasible and appropriate to do so. Similar to telehealth under the Home Health Benefit, CMS does not expect that services provided at a patient's home will usually occur during the same period as a home health episode of care, and will be monitoring claims that practitioners are billing under arrangement to ensure appropriate services are being billed by the practitioner and not being inappropriately unbundled from payments under the HH PPS.

CMS is also allowing the use of telecommunications technology by hospice physicians or NPs when visits are solely for the purpose of recertifying a patient for hospice services during the PHE for the COVID-19 pandemic.

IRF Benefit

CMS is temporarily allowing the inpatient rehabilitation facility (IRF) face-to-face visit requirements to be conducted via telehealth. This allows rehabilitation physicians to use telehealth services to conduct the required 3 physician visits per week during the PHE for the COVID-19 pandemic. Physician supervision by a rehabilitation physician may also be conducted using telehealth services.

Direct Supervision By Interactive Telecommunications Tech

CMS is allowing the requirement of any necessary direct supervision under a physician or non-physician practitioner to be fulfilled via audio/video real-time communications technology when it's indicated to reduce exposure risks for the beneficiary or health care provider during the PHE. CMS is adopting similar changes with respect to the supervision of diagnostic services furnished directly or under arrangement in a hospital or in an oncampus or off-campus outpatient department of a hospital.

PROVIDER-SPECIFIC WAIVERS

Inpatient Hospital Services Furnishes Outside Hospitals

CMS is changing the "under arrangements," or hospital subcontracting policy during the PHE for the COVID-19 pandemic beginning March 1, 2020, allowing hospitals broader flexibilities in providing inpatient services, including routine services outside the hospital. Starting March 1st, 2020, if routine services are provided under arrangements outside the hospital to its inpatients, these services are considered as being provided by the hospital.

Communications Technology In RHCs And FQHCs

CMS is expanding the use of interactive communications technology Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) in the place of in-person services that can be included in the payment for HCPCS code G0071, and updating the payment rate to reflect the addition of these services. Specifically, they are adding the following three CPT codes:

- 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)



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• 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)

Additionally, CMS is determining that any area typically served by a rural health clinic, and any area that is included in a federally qualified health center's service area plan, is automatically determined to have a shortage of HHAs and no request for this determination is required.

Homebound Status Under The Home Health Benefit

CMS defines a patient as "homebound" if it is medically contraindicated for the patient to leave the home. Patient can be considered homebound during the COVID-19 pandemic when:

- 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
- 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.

CMS will allow licensed practitioners practicing within their scope of practice, such as, but not limited to, NPs and PAs, to order Medicaid home health services during the existence of the PHE for the COVID-19 pandemic.

IRF Post-Admission Physician Evaluation Requirement

CMS is removing the post-admission physician evaluation requirement for all IRFs during the PHE for the COVID-19 pandemic in order to reduce the amount of time rehabilitation physicians in IRFs spend on completing paperwork requirements when a patient is admitted to the IRF. Additionally, the post-admission physician evaluation will not be required during the PHE. In cases where an IRF's intensive rehabilitation therapy program is impacted by the PHE, the IRF should not feel obligated to meet the industry standards but should instead make a note to this effect in the medical record.

Clinical Laboratory Fee Schedule Changes

Medicare will pay when laboratories can send trained technicians to a beneficiary's home, including a nursing home, to collect a sample for COVID-19 diagnostic testing. Medicare will pay a collection fee and for the travel. The nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is \$23.46 and for individuals in a SNF or whose samples are collected by a laboratory on behalf of an HHA is \$25.46. Medicare-enrolled independent laboratories can bill Medicare for the specimen collection fee using one of two new HCPCS codes for specimen collection for COVID-19 testing and bill for the travel allowance with the current HCPCS codes set forth in section 60.2 of the Medicare Claims Processing Manual (P9603 and P9604).

Clinical Laboratory Fee Schedule Changes

CMS is amending the teaching physician regulations in the following ways:

- General requirements for the presence of a teaching physician can be met through direct supervision by interactive telecommunications technology.
- All levels of an office/outpatient E/M service provided in primary care centers may be provided under direct supervision of a teaching physician via interactive telecommunications technology.



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- The requirement for the presence of a teaching physician during a psychiatric service in which a resident is involved may be met by the teaching physician's direct supervision via interactive telecommunications technology.
- PFS payments can be made for the interpretation of diagnostic radiology and other diagnostic tests when
 the interpretation is performed by a resident under direct supervision of a teaching physician via
 interactive telecommunications technology.
- PFS payments can be made for teaching physician services when a resident provides telehealth services to beneficiaries under the direct supervision of a teaching physician via interactive telecommunications technology.
- PFS payments can be made for services billed under the primary care exception when a resident furnishes
 telehealth services to beneficiaries under the direct supervision of the teaching physician via interactive
 telecommunications technology.

Residents' services that are not related to their approved GME programs and are performed in the inpatient setting of a hospital in which they have their training program will be considered separately billable physicians' services for which payment can be made under the PFS. CMS is also permitting hospitals to claim residents for Indirect Medical Education and Direct Graduate Medical Education purposes even when they are quarantined at home.

Remote Physiologic Monitoring

CMS is allowing RPM services to be provided to both new and established patients. Additionally, providers will only be required to obtain consent to receive RPM services once annually, including at the time services are furnished, during the duration of the PHE for the COVID-19 pandemic. Finally, CMS is clarifying that RPM codes can be used for physiologic monitoring of patients with acute and/or chronic conditions.

National And Local Coverage Determination Requirements

CMS is waiving National Coverage Determination (NCD) and Local Coverage Determination (LCD) requirements for face-to-face or in-person encounters for evaluations, assessments, certifications or other implied face-to-face services. CMS will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs. CMS is allowing chief medical officers to authorize other physician specialty or other practitioner types to meet NCD and LCD requirements for providing particular services or procedures. CMS is also allowing chief medical officers to waive NCD and LCD requirements that a physician or physician specialty to supervise other practitioners, professionals or qualified personnel.

Ambulance Origin And Destination Requirements

CMS will expand the list of destinations for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with Emergency Medical Services (EMS) protocols established by state and/or local laws where the services will be provided. 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;
- FQHCs;
- RHCs;
- Physicians' offices;



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- Urgent care facilities;
- Ambulatory surgery centers (ASCs);
- Any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available; and
- A beneficiary's home.

This expanded list of destinations will apply to medically necessary emergency and non-emergency ground ambulance transports of beneficiaries during the PHE for the COVID-19 pandemic.