



Apr 17, 2020

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CMS Issues Interim Final Rule for Medicare and Medicaid Program Revisions in Response to COVID-19 Crisis

The Centers for Medicare and Medicaid Services issued an [Interim Final Rule \("Rule"\)](#) containing, in CMS's own words, "a sweeping array of new rules and waivers of federal requirements to ensure that local hospitals and health systems have the capacity to absorb and effectively manage potential surges of COVID-19 patients."

The focus of the Rule is, in essence, "bending the rules" that are normally in place for providers so they can more readily treat patients during the public health emergency created by the COVID-19 pandemic (referred to herein as "the emergency" or "PHE"). Many of the changes deal with expanding provider capabilities through the use of telehealth and other remote communications technology in order to avoid risk of exposure to health care providers, patients, and the general public. Other topics covered by the Rule involve independent laboratory testing, ambulance transports, home health orders, "under arrangements" for hospitals, and changes in various programs in order to place patient safety above cost considerations.

The Rule was made retroactively effective back to March 1, and was published in final form in the Federal Register on April 4. CMS is accepting comments on the Rule through 5:00 p.m. EST on June 1, 2020, and may revise the Rule in response to those comments, which is the basis for its "Interim Final" status. CMS also published a [fact sheet](#) with additional background information concerning the Rule. The Rule will remain in place until the expiration or termination of the emergency.

CMS has also issued a set of [Emergency Declaration Blanket Waivers](#) of Medicare program requirements that would otherwise be applicable to various participating providers. Providers should refer to both the Rule and the blanket waivers for changes that may

affect the provider, and the provision of services during the emergency.

Additionally, CMS issued a series of provider-specific fact sheets that contain waiver and flexibilities information specific to that provider. An index to those fact sheets can be found [here](#).

Section-by-Section Summary of the Rule for Ease of Reference

A. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act: Medicare is now authorized to pay office, hospital, and other visits by physicians and other practitioners, provided via telehealth, to patients located anywhere in the country, including a patient's residence. CMS also added to the list of reimbursable Medicare telehealth services (now 80+)[1], eliminated frequency limitations and other requirements, and clarified several payment rules. Physicians providing services via telehealth should use the CPT code that best describes the nature of the care they're providing, regardless of any other factors. Also, physicians should use the place of service code they would have used if the service was provided in-person. Physicians will be reimbursed pursuant to the Physician Fee Schedule in the same amount as if they provided the service in-person. The site of service pay differential – facility (hospital) versus non-facility (physician office) – remains in effect, so the place of service is still important. In addition, CMS has added a new modifier (95) to indicate the services were provided via telehealth.

B. Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations and Required "Hands-on" Visits for ESRD Monthly Capitation Payments: Previous restrictions on the frequency of telehealth use for inpatient, nursing facility, and critical care visits have been removed, as has the requirement for a monthly face-to-face encounter for treatment for End Stage Renal Disease. Clinical assessments may now occur via telehealth. Also, patient consents may be obtained by personnel other than a physician and need not occur each time, but only annually.

C. Telehealth Modalities and Cost-sharing: Telehealth and e-visits, previously limited to established patients, may now involve new patients. Other providers, such as licensed social workers, clinical psychologists, and therapists, may now participate in, and bill for e-visits. Also, no provider will be subject to administrative sanctions for reducing or waiving any cost-sharing obligations that Federal health care program beneficiaries may owe for any service provided via interactive communications.

D. Communication Technology-Based Services (CTBS): CMS recognizes the efficiency, effectiveness, and safety of permitting telehealth and other communication technology-based services (CTBS) in a variety of settings, with various types of providers and modalities. CMS routinely pays for many types of CTBS including, but not limited to, virtual check-ins, e-visits, remote care management, and patient monitoring. CMS has now redefined interactive communications to mean any audio and video communication, including FaceTime and Skype. Additionally, the Office for Civil Rights is waiving penalties for any provider who, in good faith, violates HIPAA through the use of everyday communication technologies.

E. Direct Supervision by Interactive Telecommunications

Technology: Physician supervision, normally requiring physical presence, may now occur via telecommunications. CMS redefined “direct supervision” to include “virtual presence [of a physician] 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.” If the physician is immediately available to furnish assistance or direction, the definition applies to “incident to” services as well as diagnostic testing, along with pulmonary and cardiac rehabilitation. Physicians may also contract with other providers such as home health agencies, or infusion companies to lease their personnel to provide “incident to” services for which the physician will bill.

F. Clarification of Homebound Status under the Medicare Home Health Benefit: The emergency has forced CMS to expand the meaning of “homebound status” to include those patients who are “confined to the home” because their physician has determined it is

“medically contraindicated” for them to leave. Those with confirmed or suspected cases of COVID-19 and those patients who are elderly, or who have comorbid conditions making them more susceptible to the virus will fall into that category. However, a physician must certify that leaving home is medically contraindicated, and assessments must be performed to confirm that the proposed service is appropriate and medically necessary. In addition, all other requirements for reimbursement for home care must be satisfied. The patient must be: (i) under a physician’s care; (ii) under a plan of care that is periodically reviewed by the physician; and (iii) in need of skilled care or therapy services. A patient simply exercising self-quarantine would not qualify, and a visit to obtain a throat culture likewise would not be considered necessary home care. Whether a patient is homebound and needs skilled services must be based on an assessment of each beneficiary’s individual condition and care needs. CMS indicated that this “clarification” is not limited to current circumstances, but also will apply during outbreaks of other infectious diseases and, more broadly, in instances where the condition of a patient makes it medically contraindicated for the patient to leave his or her home.

G. The Use of Technology Under the Medicare Home Health

Benefit During the PHE for the COVID-19 Pandemic: Allows home health agencies (HHAs) to use various types of technology in conjunction with the provision of in-person visits. Although technology may not substitute for an in-person home visit ordered as part of the plan of care, the use of technology may result in changes to the frequency or types of visits outlined in the plan of care, especially to treat COVID-19 patients. The Rule includes a discussion of technology examples that can be leveraged for providing care in the home setting.

H. The Use of Telecommunications Technology Under the

Medicare Hospice Benefit: Hospices may provide services via a telecommunications system if it is feasible and appropriate to do so without jeopardizing the patient’s health, or the health of those who are providing the care services. The use of such technology must be included in the plan of care, and must be tied to patient-specific needs as identified in the comprehensive assessment and measurable outcomes the hospice anticipates will occur.

I. Telehealth and the Medicare Hospice Face-to-Face Encounter

Requirement: Regulations have been amended to allow telecommunications technology to be used by the treating provider for a face-to-face visit when such a visit is solely for the purpose of recertifying a patient for hospice services during the emergency. The technology must include, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site hospice physician or nurse practitioner.

J. Modification of the Inpatient Rehabilitation Facility (IRF)

Face-to-Face Requirement for the PHE During the COVID-19

Pandemic: The existing medical supervision requirement for IRF patients means a rehabilitation physician must conduct face-to-face visits with the patient at least three days per week throughout the patient's stay. While face-to-face visits are encouraged, during the emergency, the face-to-face visits may be conducted via telehealth.

K. Removal of the IRF Post-Admission Physician Evaluation

Requirement for the PHE for the COVID-19 Pandemic and

Clarification Regarding the "3-Hour" Rule: At the time of admission to an IRF, a physician must certify in the patient's record that the patient is reasonably expected to meet all of the regulatory requirements for admission. This must be completed in the patient's record within 24 hours of admission. This requirement is being waived during the emergency. However, this waiver does not preclude such an evaluation if the physician believes it is warranted. Another requirement is that IRF patients are reasonably expected to benefit from at least three hours of therapy, five days per week, which is known as the three-hour rule. It is recognized, though, that it may be difficult to meet this requirement due to staffing issues during the emergency. Therefore, if an IRF is so impacted, it does not have to meet this standard, but should note in the medical record as to the cause for not meeting the standard.

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

- Virtual communications furnished by RHCs and FQHCs are being expanded. Three additional CPT codes, 99421, 99422, and 99423, can be provided through an online visit (i.e., an “E-visit”), which is a non-face-to-face, patient-initiated communication using online patient portals, and the face-to-face visit requirements for these codes will be waived during the emergency. These virtual communication services will also be available to new patients who were not seen at the RHC or FQHC during the prior twelve months. During the emergency, prior beneficiary consent can be obtained at the time the services are furnished, as long as the consent is obtained before the services are billed.
- For visiting nurse services furnished in the home by RHCs and FQHCs, a number of requirements are being waived during the emergency, and any area typically served by the RHC or FQHC is being automatically deemed to have a shortage of home health agencies (HHAs). However, the RHC or FQHC should check the HIPAA Eligibility Transaction System (HETS) first to ensure the patient in question is not already under a home health care plan.

M. Medicare Clinical Laboratory Fee Schedule: Payment for Specimen Collection for Purposes of COVID-19 Testing: Medicare will pay a higher specimen collection fee, and associated travel allowance to independent laboratories for collection of COVID-19 testing specimens for homebound and non-hospital patients. These can be collected from SNF residents and on behalf of HHAs. Although nominal (\$23.46 for general specimen and \$25.46 for a SNF patient or on behalf of an HHA), the fees are a material increase over the current rates of \$3 and \$5. The COVID-19 testing specimens must be collected by trained laboratory personnel, and are not a type that only require the services of a messenger or specimen pick-up service. Two new level II codes are being established, one for collection from any specimen source, and one for collection from an SNF patient or on behalf of an HHA. Payment will also be made for the travel allowance associated with such specimen collection activities. There is no longer a requirement that labs maintain paper logs to document travel and may do so using digital documentation.

N. Requirements for Opioid Treatment Programs (OTP): The therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, may be furnished using audio-only telephone calls rather than two-way interactive audio-video communication during the emergency if patients do not have access to two-way audio/video technology, provided all other requirements are met.

O. Application of Teaching Physician and Moonlighting Regulations During the Emergency for the COVID-19 Pandemic:

- During the emergency, the presence of a teaching physician can be met through direct supervision by interactive telecommunications technology. All levels of an office/outpatient service provided in primary care centers may be provided under direct supervision of the teaching physician by interactive telecommunications technology. Also permitted using such technology is the direct supervision component for diagnostic radiology, diagnostic tests, and psychiatry services. However, such supervision is not permitted for surgical, high risk, interventional, or other complex procedures.
- During the emergency, Medicare will pay under the physician fee schedule for teaching physician services when a resident furnishes telehealth services to beneficiaries under the direct supervision of a teaching physician, which may be provided by interactive telecommunications technology. This is also applicable for services billed under the primary care exception by the teaching physician.
- During the emergency, Medicare will pay under the physician fee schedule for teaching physician services when a resident is furnishing those services while in quarantine, if there is direct supervision by the teaching physician through interactive telecommunications technology.
- During the emergency, services of residents that are not related to their approved GME programs but are performed in the inpatient setting of the hospital where they have their training program will be construed as separately billable physicians' services.

P. Special Requirements for Psychiatric Hospitals (§ 482.61(d)):

Non-physician practitioners (NPPs) will be allowed to document progress notes of patients receiving services in psychiatric hospitals in addition to MDs and DOs, as previously allowed.

Q. Innovation Center Models:

- The Medicare Diabetes Prevention Program (MDPP) is amended to permit certain beneficiaries to obtain the set of MDPP services more than once per lifetime (allowing patients who may have ceased participation during the pandemic to re-enroll in the program), increase the number of virtual make-up sessions, and allow certain MDPP suppliers to deliver virtual MDPP sessions on a temporary basis.
- A 3-month extension was implemented to the Comprehensive Care for Joint Replacement (CJR) Model to extend performance year (PY) 5 such that the model now ends on March 31, 2021, rather than December 31, 2020. In addition, CMS modified the CJR's "extreme and uncontrollable circumstances policy," so that the policy applies to episodes of care impacted by the pandemic.

R. Remote Physiologic Monitoring (RPM): CMS finalized, on an interim basis during the emergency, that consent to receive RPM services can be obtained once annually, including at the time services are furnished, during the duration of the emergency. CMS also clarified that RPM codes can be used for physiologic monitoring of patients with acute conditions, such as an acute respiratory virus, as well as for patients with chronic conditions like high blood pressure or COPD.

S. Telephone Evaluation and Management (E/M) Services: In order to support the use of audio-only communications between practitioners and patients, CMS finalized, on an interim basis for the duration of the emergency, separate payment for CPT codes 98966–98968 and COPT codes 99441–99443. Furthermore, CMS will not conduct reviews to consider whether services billed under these codes were furnished to established patients versus new patients.

T. Physician Supervision Flexibility for Outpatient Hospitals – Outpatient Hospital Therapeutic Services Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS)

Level of Supervision: CMS assigned, on an interim basis during the emergency, all outpatient hospital therapeutic services that fall under § 410.27(a)(1)(iv)(E) a minimum level of supervision consistent with the minimum default level of general supervision that applies for most outpatient hospital therapeutic services.

U. Application of Certain National Coverage Determination (NCD) and Local Coverage Determination (LCD) Requirements During the PHE for the COVID-19 Pandemic:

- On an interim basis during the emergency, CMS finalized that, to the extent an NCD or LCD would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications, or other implied face-to-face services, those requirements will not apply during the emergency.
- To allow practitioners maximum flexibility in caring for their patients, during the emergency CMS will not enforce the clinical indications for coverage across respiratory, home anticoagulation management, and infusion pump NCDs and LCDs.
- To accommodate staff shortages, to the extent that NCDs and LCDs require a physician or physician specialty to supervise other personnel, the chief medical officer of the facility can authorize that such supervision requirements to not apply during the emergency.

V. Change to Medicare Shares Savings (MSSP) Extreme and Uncontrollable Circumstances Policy: CMS extended the 2019 MIPS data submission deadline to April 30, 2020, and also modified the MIPS “automatic extreme and uncontrollable circumstances” policy so that it will apply to MIPS-eligible clinicians who do not submit their MIPS data by the extended deadline.

W. Level Selection for Office/Outpatient E/M Visits When Furnished Via Medicare Telehealth: On an interim basis during the emergency, CMS revised its policy to specify that the office/outpatient E/M level selection, when furnished via telehealth,

can be based on medical decision-making (MDM) or time, with “time” defined as all time associated with the E/M on the day of the encounter, and to remove requirements regarding documentation of history and/or physician exam in the medical record. (CMS notes that this policy is similar to the one that will apply to all office-outpatient E/Ms beginning in 2021.)

X. Counting of Resident Time During the PHE for the COVID-19

Pandemic: During the emergency, CMS is permitting a hospital paying a resident’s salary and fringe benefits for the time the resident is at home, or in the home of an existing patient, to claim that resident for IME and DGME purposes.

Y. Addressing the Impact of COVID-19 on Part C and Part D

Quality Rating Systems: Due to concerns that the emergency will pose challenges to data collection, CMS is modifying regulations in parts 417, 422, and 423 to eliminate requirements for the collection of HEDIS and CAHPS data that would otherwise occur in 2020. CMS intends to use the 2020 measure-level stars and scores for the missing HEDIS and CAHPS data. So as not to inappropriately incentivize actions by providers that are not necessary during the emergency, CMS is delaying the application of the guardrails that were set to begin with the 2023 Star Ratings to be produced in October 2022.

Z. Changes to Expand Workforce Capacity for Ordering Medicaid Home Health Nursing and Aide Services, Medical Equipment, Supplies and Appliances and Physical Therapy, Occupation Therapy or Speech Pathology and Audiology

Services: CMS amended 42 CFR § 440.70 to allow licensed practitioners practicing within their scope of practice such as NPs and PAs to order Medicaid home health services during the emergency.

AA. Origin and Destination Requirements Under the Ambulance

Fee Schedule: On an interim basis during the emergency, CMS expanded the list of destinations at 42 CFR § 410.40(f) 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 protocols established by state and/or local laws where the

services will be furnished.

BB. Merit-based Incentive Payment System (MIPS) Updates: For the CY 2020 performance period, CMS added a new activity to the Improvement Activities Inventory which promotes clinician participation in a clinical trial utilizing a drug or biological product to treat patients with COVID-19. For this activity, CMS made a one-time exception to its established Annual Call for Activities timeframe and processes. CMS also extended the deadline to apply for re-weighting the quality, cost, and improvement activities performance categories, but extension applications must demonstrate the clinician has been adversely affected by the emergency.

CC. Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency for the COVID-19 Pandemic: CMS changed its “under arrangements” policy during the emergency, so hospitals have more flexibility to furnish inpatient services, including routine services, outside the hospital. CMS emphasized that hospitals need to continue to exercise sufficient control and responsibility over the use of hospital resources in treating their patients, regardless of whether the treatment occurs in the hospital or outside the hospital “under arrangements.”

DD. Advance Payments to Suppliers Furnishing Items and Services under Part B: CMS modified its existing advance payment rules at 42 CFR 421.214 to increase the limit on advanced payments from 80% to 100% of the anticipated payment for a claim, based upon historical assigned claims payment data for claims paid to the supplier. However, any suppliers in bankruptcy will not be eligible to receive advanced payments.

If you have any questions, contact [Rhonda Frey](#), [Rhonda Schechter](#), [Jim Dietz](#), or any attorney in the [Health Care Innovation](#) Industry Team.

To provide guidance and support to clients as this global public-health crisis unfolds, Frost Brown Todd has created a [Coronavirus Response Team](#). Our attorneys are on hand to answer your questions and provide guidance on how to proactively prepare for and manage any coronavirus-related threats

to your business operations and workforce.

[1] The list is of eligible services is available at:
<https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

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