

## Summary of April 30 Interim Final Rule with Comment Period in Response to the COVID-19 Public Health Emergency

On April 30, the Centers for Medicare and Medicaid Services (CMS) promulgated a second interim final rule with comment period (IFC) and additional waivers to ensure the healthcare system can respond to the public health threats posed by COVID-19. The changes in this IFC address issues raised by the first IFC, support the expansion of testing, improve access to telehealth services, and reduce the regulatory burden on providers. A link to the rule can be found [here](#). The regulations are retroactively applicable beginning March 1, 2020.

A summary of these key changes follows. Note that these apply to the Medicare program only and private insurers may not adopt these changes.

### B. Scope of Practice (pg. 19)

#### *Supervision of Diagnostic Tests by Certain Nonphysician Practitioners (NPPs)*

For the duration of the Public Health Emergency (PHE), CMS will allow certain NPPs (NPs, CNSs, PAs and CNMs) flexibility to practice to the extent authorized by their State scope of practice laws. This will allow these practitioners to order, furnish directly, and supervise the performance of diagnostic tests, subject to applicable state law.

#### *Therapy --- Therapy Assistants Furnishing Maintenance Therapy (PFS)*

Under Medicare Part B, CMS will allow physical therapists (PTs) or occupational therapists (OTs) who established a maintenance program to delegate the performance of maintenance therapy services to a PT or OT assistant when clinically appropriate.

#### *Therapy --- Student Documentation*

In order to increase the availability of clinicians available to provide care during the PHE, CMS announced a general policy that there is broad flexibility for all members of the medical team to add documentation in the medical record, which is then reviewed and signed by the appropriate clinician. In particular, for the duration of the PHE, 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, may review and verify, 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.

#### *Pharmacists Providing Services Incident to a Physicians' Service*

CMS clarifies that pharmacists fall within the regulatory definition of auxiliary personnel who may provide services incident to the services of the billing physician or NPP, and under the appropriate supervision, if payment for the services is not made under Part D.

### C. Modified Requirements for Ordering COVID-19 Diagnostics Laboratory Tests (pg. 27)

In order to expand testing capacity, CMS is removing the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. During the PHE, tests may be covered when ordered by any health care professional authorized to do so under state law. CMS is also removing

the same ordering requirements for a diagnostic laboratory test for influenza virus or respiratory syncytial virus (RSV) as symptoms may be similar as for COVID-19. CMS has included a list of diagnostic lab tests for which the ordering requirement has been removed, available [here](#). This only applies to influenza or RSV diagnostic test that are “furnished in conjunction with a COVID-19 diagnostic laboratory test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis or of identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection;” unrelated or repeat testing is not considered medically necessary.

If a COVID-19 test is furnished without a physician or NPP’s order, the laboratory that conducts the test is required to directly notify the patient of the results, and to meet other applicable test result reporting requirements, including reporting to local public health officials.

#### E. Treatment of Certain Relocating Provider-based Departments during the COVID-19 PHE (pg. 33)

CMS adopted a temporary extraordinary circumstances relocation exception policy for excepted off-campus provider-based departments (PBD) that relocate off-campus during the PHE. The agency is extending the temporary policy to on-campus PBDs that relocate off-campus during the PHE and will allow the relocating PBDs to continue to be paid under the OPPS (as opposed to the PFS). CMS also streamlined the process for relocating PBDs to obtain the temporary extraordinary circumstances policy exception.

#### F. Furnishing Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (Including the Patient’s Home) (pg. 44)

CMS clarified that hospital and community mental health center (CMHC) staff can furnish certain outpatient therapy, counseling, and educational services (including partial hospitalization program (PHP) services) incident to a physician’s service during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location using telecommunications technology. In these circumstances, the hospital can furnish services to a beneficiary in a temporary expansion location (including the beneficiary’s home) if that beneficiary is registered as an outpatient. The CMHC is able to furnish services in an expanded CMHC (including the beneficiary’s home) to a beneficiary who is registered as an outpatient.

The agency also clarified that hospitals can furnish clinical staff services (for example, drug administration) in the patient’s home, which is considered provider-based to the hospital during the COVID-19 PHE, and to bill and be paid for these services when the patient is registered as a hospital outpatient. Further, when a patient is receiving a professional service via telehealth in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service.

#### G. Medical Education (pg. 60)

##### *Indirect Medical Education (IME)*

In order to give hospitals, inpatient rehabilitation facilities (IRF) and inpatient psychiatric facilities (IPFs) that provide services to Medicare beneficiaries flexibility to respond to COVID-19, CMS is changing policies to remove restrictions in IME or teaching status adjustment payment amounts during the PHE.

In particular, CMS will hold teaching hospitals harmless from reductions in IME payments due to increases in bed counts due to COVID-19. The agency will exclude beds temporarily added during the PHE from calculations to determine IME payment amounts. CMS is also revising its policy to ensure that teaching IRFs and IPFs can take patients from inpatient acute care hospitals without being penalized with lower teaching status adjustments. For the duration of the PHE, an IRF's or IPF's teaching status adjustment payment amount will be the same as it was on the day before the PHE was declared.

#### *Time Spent by Residents at Another Hospital During the COVID-19 PHE*

CMS is revising its direct graduate medical education (DGME) policy to allow teaching hospitals to claim the time spent by residents training at other hospitals for the duration of the PHE. This policy will apply as long as the following requirements are met:

- (1) The sending hospital sends the resident to another hospital in response to the COVID-19 pandemic.
- (2) Time spent by the resident at the other hospital would be considered to be time spent in approved training if the activities performed by the resident are consistent with guidance for the approved medical residency program at the sending hospital.
- (3) The time that the resident spent training immediately prior to and/or subsequent to the timeframe that the PHE was in effect was included in the sending hospital's FTE resident count.

CMS has also waived certain requirements under the Medicare conditions of participation at Sec. 482.41 and 485.623, and time spent by residents at locations at locations that meet these requirements will not be treated differently from time spent by residents at the hospital prior to the PHE.

#### I. Durable Medical Equipment (DME) Interim Pricing in the CARES Act (pg. 69)

CMS implements Section 3712 of the CARES Act, which prevents the scheduled decrease in payment amounts for durable medical equipment (DME) by revising the fee schedule amounts for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs other than former CBAs through the duration of the PHE. A list of product categories included in the DMEPOS CBP can be found [here](#).

#### L. Medicare Shared Savings Program (pg. 83)

CMS is modifying the Medicare Shared Savings Program (MSSP) policies to address the impact of the COVID-19 PHE and encourage continued participation by Accountable Care Organizations (ACOs). The agency outlined the following changes to the MSSP:

- According to CMS, there are currently 160 ACO Shared Savings Program participation agreements that will end on December 31, 2020. The changes outlined in this IFC will allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by one year.
- ACOs in the BASIC track may elect to maintain their current level of participation for performance year (PY) 2021.
- CMS clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE. According to the agency, "under the existing extreme and uncontrollable circumstances policies for the Shared Savings Program, the timeframe for the extreme and uncontrollable circumstance of the COVID-19 pandemic for

purposes of mitigating shared losses will extend for the duration of the COVID-19 PHE.” If the PHE lasts 6 months, any shared losses an ACO encounters for PY 2020 would be reduced by one-half.

- The agency made adjustments to program calculations to mitigate the impact of COVID-19 on ACOs. All Part A and Part B Fee-for-Service payment amounts for an episode of care for treatment of COVID-19, triggered by an inpatient service, and as specified on Part A and Part B claims with dates of service during the episode, will be excluded from Shared Savings Program calculations.
- CMS is expanding the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication.

#### M. Additional Flexibility under the Teaching Physician Regulations (pg. 130)

CMS updated the list of services included under the primary care exception (PCE) on an interim basis for the duration of the PHE. Medicare may make payment to the teaching physician for the following services when furnished by a resident under the PHE:

##### *Services Included in the March 31 IFC:*

- New and established office/outpatient E/M codes (99201-99205 and 99211-99215)  
Wellness visit codes (G0402, G0438-G0439)

##### *Services Added to the April 30 IFC:*

- Telephone E/M codes (99441-99443)
- Translational Care Management (TCM) codes (99495 and 99496)
- E-visit codes (99421-99423)
- Virtual check-in codes (G2010 and G2012)
- Interprofessional consultation code (99452)

CMS recognizes that there are circumstances where the physical presence of the teaching physician may be impossible as he or she may be at home, under quarantine, etc. In the March 30 IFC, CMS did not specify that the direct supervision requirement could be fulfilled immediately after the patient visit. In response to stakeholder concern and requests for clarity, CMS is revising regulations on an interim basis that the teaching physician may not only direct the care furnished by residents, but he or she may also review the services provided by the resident during or immediately following the visit via audio/video real time communications technology.

#### N. Payment for Audio-Only Telephone Evaluation and Management Services (pg. 137)

In response to stakeholders’ concern that the intensity of furnishing an audio-only visit to beneficiaries during the COVID-19 PHE is not accurately captured by the valuation of the telephone E/M services established in the March 31 IFC, CMS is finalizing new RVUs for these services based on the RVUs associated with the level 2-4 established office/outpatient E/M visits. On an interim basis for the duration of the COVID-19 PHE, CMS is crosswalking CPT codes 99212, 99213, and 99214 to CPT codes 99441, 99442, and 99443, respectively. CMS is also crosswalking the direct PE inputs associated with

these codes. The telephone E/M services have been added to the list of Medicare telehealth services for the duration of the PHE and CMS separately issued a Section 1135 waiver for these services.

| CPT Code | Total Facility RVUs | Total Payment |
|----------|---------------------|---------------|
| 99441    | 0.73                | \$26.35       |
| 99442    | 1.45                | \$52.33       |
| 99443    | 2.23                | \$80.48       |

#### O. Flexibility for Medicaid Laboratory Services (pg. 141)

CMS believes that it is important for Medicaid beneficiaries to have broad access to tests to detect the SARS-CoV-2 virus and/or antibodies to the SARS-CoV-2 virus. Therefore, CMS is providing coverage of COVID-19 tests, including tests administered in non-office settings and coverage for the laboratory processing of self-collected COVID-19 tests that are FDA-approved for self-collection. These flexibilities would be applicable for the COVID-19 PHE and future PHEs resulting from an outbreak of communicable disease.

#### R. Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria (pg. 153)

CMS reports that over 50 percent of the QCDRs approved for the 2020 performance year (PY) are supported by specialty societies that represent and support clinicians on the front lines of the COVID-19 pandemic. CMS does not wish to burden these clinicians with having to submit data to a QCDR so they are amending the QCDR measure approval criteria outlined in the CY 2020 PFS final rule. CMS is delaying the implementation date for the completion of QCDR measure testing by one year. Specifically, beginning with the 2022 PY (previously 2021), all QCDR measures must be developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. During this one-year delay, CMS will review QCDR measures to ensure they are still valid, reliable, and align with the goals of the Meaningful Measure initiative. CMS is also delaying the collection of data on QCDR measures by one year. Beginning with the 2022 PY (previously 2021), QCDRs will be 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.

#### S. Application of Certain National Coverage Determination and Local Coverage Determination Requirements during the PHE for the COVID-19 Pandemic (pg. 157)

CMS finalized that National Coverage Determination (NCD) and Local Coverage Determination (LCD) requirements for face-to-face, in-person, or other implied face-to-face services would not apply during the COVID-19 PHE in the IFC published on March 30. In that rule, the agency also finalized policy that it would not enforce the clinical indications across respiratory, home anticoagulation management, and infusion pump NCDs and LCDs. However, none of these changes waive medical necessity requirements and providers must continue to document medical necessity for all services.

In this IFC, the agency states that they will not enforce the clinical indications for therapeutic continuous glucose monitors (CGMs) in LCDs. This means the agency will not enforce the clinical indications restricting the type of diabetes that a beneficiary must have or the requirement that a beneficiary must

demonstrate need for frequent blood glucose testing in order to permit COVID-19 infected patients with diabetes to receive a Medicare covered therapeutic CGM.

V. COVID-19 Serology Testing (pg. 168)

FDA-authorized COVID-19 serology testing to detect SARS-CoV-2 antibodies will be covered by the Medicare program on an interim basis as they fall under the diagnostic laboratory test benefit category. Coverage outside of a PHE would be established through the NCD process, but CMS sees a need to establish timely and uniform coverage during the PHE. The agency expects to be billed once per sample when clinically indicated.

Z. Time Used for Level Selection for Office/Outpatient Evaluation and Management Services Furnished Via Medicare Telehealth (pg. 182)

In the March 30 IFC, CMS finalized policy to allow providers to select office/outpatient evaluation and management (E/M) visit level when furnished via telehealth by time or medical decision making (MDM) on the date of service. There was confusion because there was a discrepancy between the times for these services listed in the public use file and those listed in the code descriptor. The agency is finalizing policy to allow providers to select the E/M visit level based on the time of the code descriptor during the PHE.

AA. Updating the Medicare Telehealth List (pg. 182)

CMS added a number of services to the Medicare telehealth list in the March 30 IFC, but is modifying the process to add or delete services from this list to expedite it during the PHE. The agency will allow services to be added to the list on a subregulatory basis by posting new services on the web list of telehealth services when the agency receives a request to add a service that can be furnished in full by a distant site practitioner to a beneficiary in a manner that is similar to the in-person service. The additional services added through this expedited process will only be on the list during the PHE. An updated list of services payable under the Medicare PFS when furnished via telehealth can be found [here](#).

BB. Payment for COVID-19 Specimen Collection to Physicians, Nonphysician Practitioners, and Hospitals (pg. 184)

CMS is providing additional payment for assessment and COVID-19 specimen collection to support testing. The agency established policy in the March 30 IFC to pay a nominal specimen collection fee and a travel allowance to independent laboratories for specimen collection for patients who are homebound or inpatients not in a hospital. They believe this original policy did not describe the services provided in the context of large-scale dedicated testing operations involving a physician or NPP delivered to new patients. While CPT code 99211 applies to patients with whom providers have established relationships, in the context of this PHE, CMS has determined it can be used for new patients when a provider delivers symptom and exposure assessment along with specimen collection. For hospital outpatient departments (HOPDs), the agency is creating a new E/M code solely to support COVID-19 testing for the PHE:

- HCPCS code C9803: Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source

This new code will be assigned to APC 5731 Level 1 Minor Procedures and will have a status indicator “Q1” to indicate this service will be conditionally packaged under the OPPS when billed with a separately payable primary service in the same encounter.

There will be no cost sharing for CPT code 99211 or HCPCS code C9803.

CC. Payment for Remote Physiological Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency (pg. 192)

CPT coding guidance for the RPM code 99454 prohibits reporting for monitoring for fewer than 16 days during a 30-day period while RPM CPT codes 99091, 99453, 99457, and 99458 all have 30-day reporting periods. Many COVID-19 patients do not require 16 days of monitoring. Therefore, CMS will allow RPM monitoring services to be reported to Medicare for periods shorter than 16 of 30 days, but no less than 2 days, as long as the other billing requirements are met. The agency is not making changes to the payment for these services.