



On April 30, the Centers for Medicare and Medicaid Services (CMS) issued an [Interim Final Rule](#) with comment period (IFC) in order to allow individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the 2019 Novel Coronavirus (COVID-19). The American College of Radiology has prepared a detailed summary of this rule outlining the provisions with a potential impact on radiology practices. This is the second IFC issued by CMS to address the COVID-19 public health emergency (PHE).

### **Scope of Practice**

In December 2019, CMS issued a request for feedback in response to part of the President’s Executive Order (EO) 13890 on “Protecting and Improving Medicare for Our Nation’s Seniors,” seeking stakeholders guidance in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license.

#### *Supervision of Diagnostic Tests by Certain Nonphysician Practitioners*

In response to the request for feedback discussed above, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise diagnostic tests because they are currently authorized to do so under State scope of practice rules. CMS received feedback from the radiology community that did not support making any changes to CMS regulations that would result in any inappropriate expansion of the role of non-physician practitioners (NPPs). Currently under CMS policy, only physicians are generally permitted to supervise diagnostic tests. CMS is finalizing on an interim basis changes to add flexibility for NPPs.

CMS will permit on an interim basis NPP’s to furnish services that would typically be furnished by a physician and be paid under Medicare Part B for the professional services they furnish directly and “incident to” their own professional services, to the extent authorized under their State scope of practice laws. This interim change will allow these practitioners to order, furnish directly, and supervise the performance of diagnostic tests, subject to applicable state law, during the PHE.

Additionally, CMS is amending the regulation to specify in the basic rule that diagnostic tests must be furnished under the appropriate level of supervision by a physician during the PHE, by a NP, CNS, PA, and CNM. Also, CMS is amending regulation to allow diagnostic tests to be performed by a PA without physician supervision when authorized to perform the tests under applicable state law. Similarly, CMS is amending regulation regarding the levels of supervision, to also authorize NPs, CNSs, PAs, and CNMs during the PHE to provide the appropriate level of supervision assigned to diagnostic tests.

CMS is seeking public feedback indicating the number of states with more flexible scope of practice rules than federal regulations to help CMS understand the scope of impact of these changes.



## **Treatment of Certain Relocating Provider-Based Departments During the COVID-19 PHE**

CMS continues to believe the current extraordinary circumstances policy is appropriate under normal circumstances, but wishes to provide flexibility to allow hospitals to respond effectively to the public health threats posed by the COVID-19 PHE. Under the temporary extraordinary circumstances relocation exception policy for on-campus and excepted off-campus provider-based departments (PBDs) that relocate off-campus in response to the PHE, CMS permits the PBDs that relocate to continue to be paid under the Hospital Outpatient Prospective Payment System (OPPS). CMS is adopting a temporary relocation exception policy specific to the PHE for the COVID-19 pandemic so that hospitals can maintain treatment capacity and deliver needed care for patients. CMS believes that overall there will be minimal change in the types of patients treated under these policies compared to the absence of these policy changes.

## **Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (including the Patient's Home)**

CMS created regulatory flexibilities in response to the COVID-19 PHE, including publishing the March 31st COVID-19 IFC, issuing numerous blanket waivers of requirements for health care providers under section 1135 of the Act, and exercising the authority granted under section 1812(f) of the Act. CMS continues to believe that it is important for beneficiaries to be able to receive care in temporary expansion locations to contain infection. CMS received many questions about how hospital outpatient services can be furnished when the patient is in a temporary expansion location, including his or her home. CMS received questions regarding those hospital outpatient services that typically do not co-occur with a physician or NPP furnishing a professional service. Those services are billed only under the hospital OPPS when furnished by the hospital and there is no professional service that is separately billable under the Physician Fee Schedule (PFS). Additionally, CMS received questions about how the hospital should bill during the COVID-19 PHE when the practitioners typically furnishing services in HOPDs are now instead furnishing professional services as Medicare telehealth services.

CMS clarified that hospital and Community Mental Health Center (CMHC) staff can furnish certain outpatient therapy, counseling, and educational services, including 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. CMS also clarified that hospitals can furnish clinical staff services, like drug administration, in the patient's home, which is considered provider-based to the hospital during the COVID-19 PHE. Providers are able to bill and be paid for these services when the patient is registered as a hospital outpatient. Further, CMS clarified that 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.



## **Update to the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy**

The Extraordinary Circumstances Exceptions (ECE) policy under the Hospital Value-based Purchasing (VBP) Program allows CMS to grant exceptions to hospitals affected by an extraordinary circumstance without a request form. CMS is modifying the Hospital VBP Program's ECE policy to allow CMS to grant ECE exceptions to hospitals which have not requested them when CMS determines that an extraordinary circumstance that is out of the hospitals control, such as an act of nature or PHE, which affects an entire region, in addition to retaining the individual ECE request policy.

CMS is granting exceptions under their updated policy to all hospitals participating in the Hospital VBP Program with respect to certain 4<sup>th</sup> quarter 2019 measure data that hospitals would otherwise be required to report in April or May of 2020, and measure data that hospitals would otherwise be required to collect during the 1<sup>st</sup> and 2<sup>nd</sup> quarters of 2020.

## **Updating the Medicare Telehealth List**

CMS believes that, for purposes of the PHE for the COVID-19 pandemic, the process established for adding or deleting services from the Medicare telehealth services list should be modified to allow for an expedited process during the PHE that does not involve notice and comment rulemaking. Therefore, for the duration of the PHE for the COVID-19 pandemic, CMS is revising its regulation to allow the use of a subregulatory process to modify the services included on the Medicare telehealth list. CMS is not codifying a specific process to be in effect during the PHE for the COVID-19 pandemic. Rather, CMS will be able to add services to the Medicare telehealth list on a subregulatory basis by posting new services to the web listing of telehealth services when the agency receives a request to add or identifies through internal review 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. These procedures and services will remain on the list only during the PHE for the COVID-19.

## **Rural Health Clinics (RHCs)**

Rural Health Clinics (RHCs) provide services in rural areas that are deemed medically underserved or medical professional shortage areas. RHCs are paid an all-inclusive rate for medically necessary, face-to-face visits with an RHC practitioner. There is an RHC payment limit, which is determined by the Medicare Economic Index, and an RHC that is provider-based to a hospital with fewer than 50 beds is exempt from the national per-visit payment limit. Due to the COVID-19 pandemic, hospitals have or are planning to increase inpatient bed capacity. On an interim basis, CMS is implementing a change to the period of time used to determine the number of beds in a hospital for purposes of determining which provider-based RHCs are subject to the payment limit. For the duration of the PHE, CMS 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 this policy. As a result, RHCs that were exempt prior to the PHE will continue to be exempt from the national per-visit payment limit.



## **Medicare Shared Savings Program (MSSP)**

The COVID-19 pandemic has created concern for Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) participants surrounding expenditure and utilization changes, as well as benchmarks. Additionally, for those participating under performance-based risk, there are uncertainties with potential liability for shared losses and disrupting public health activities. CMS has modified the Shared Savings Program to: 1) allow ACOs whose current agreement periods expire on December 31, 2020 the option to extend 1 year, and allow ACOs in the BASIC track to maintain their current level of participation in PY2021, 2) clarify the program's extreme and uncontrollable circumstances policy, 3) adjust calculations to mitigate the impact of COVID-19 on ACOs, and 4) expand the definition of primary care services for beneficiary assignment to include telehealth codes.

### *Application Cycle for January 1, 2021 Start Date and Extension of Agreement Periods Expiring on December 31, 2020*

CMS is forgoing the application cycle for a January 1, 2021, start date to allow current MSSP participants to continue to focus on providing COVID-19 care during the pandemic. By forgoing the 2021 application cycle, CY 2020 will not serve as a benchmark year 3 for ACOs that would have started on January 1, 2021.

Additionally, ACOs that entered a first or second agreement with start date January 1, 2018, may extend their agreement for an optional fourth performance year. Voluntary extension will allow ACOs to remain under their existing benchmark for another year, and therefore increase stability and predictability given the impacts of the pandemic.

CMS seeks comment on their approach for the extension of participation agreements scheduled to expire December 31, 2020.

### *Allow BASIC Track ACOs to Elect to Maintain their Participation Level for One Year*

CMS is concerned that some of the care coordination processes ACOs have been developing may be interrupted by the pandemic, and acknowledges that many ACOs do not know the overall impacts on expenditures and potential losses of the PHE. As a result, CMS is allowing MSSP participants on the BASIC track to elect to maintain their current level under the BASIC track for PY 2021. For PY 2022, an ACO that elects this option will move to the track it would have been participating in in PY 2022 if it had advanced automatically to the next level for PY 2021. CMS will release additional guidance surrounding form, manner, and timeframe for making this election.

CMS seeks comments on the advancement deferral option they are establishing in the IFC.



### *Applicability of Extreme and Uncontrollable Circumstances Policies to the COVID-19 Pandemic*

CMS clarified that for purposes of the MSSP, the months affected by extreme and uncontrollable circumstances will begin with January 2020 (consistent with the fact that the COVID-19 pandemic was determined to exist nationwide as of January 27, 2020 and announced by the Secretary on January 31, 2020) and will continue through the end of the PHE (which includes any subsequent renewals). In CMS' March 31<sup>st</sup> IFC, the Agency established that it will reduce the amount of an ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of total months in the performance year affected by extreme and uncontrollable circumstance, and the percentage of the ACO's beneficiaries that reside in an area affected by extreme and uncontrollable circumstances.

Currently, the COVID-19 PHE has covered 4 months (January 2020-April 2020), and in the event that it lasts all of CY 2020, all shared losses for PY 2020 will be mitigated for ACOs participating in performance-based risk tracks. Similarly, if the PHE were to last until June 2020, shared losses would be reduced by one half.

### *Adjustments to Shared Savings Program Calculations to Address the COVID-19 Pandemic*

CMS believes it is necessary to revise policies on MSSP financial calculations to mitigate the impact of unanticipated increased expenditures related to COVID-19 care. Therefore, CMS is revising its policy to exclude from Shared Savings Program calculations all Parts A and B fee-for-service (FFS) payment amounts for an episode of care for treatment of COVID-19, triggered by an inpatient service, and as specified by Parts A and B claims with dates of service during the episode. CMS will remove COVID-19 related expenditures from the determination of benchmark expenditures and determination of performance year expenditures. Additionally, CMS will exclude the affected months from total person years used in the per capita expenditure calculations.

Under this revision, an episode of care will be triggered by an inpatient service for treatment of COVID-19 based on discharges for inpatient services eligible for the 20% DRG adjustment, or discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the Inpatient Prospective Payment System (IPPS) when the date of admission falls within the PHE.

CMS seeks comment on their approach to adjusting program calculations to mitigate the financial impact of the COVID-19 PHE on ACOs.

### *Expansion of Codes Used in Beneficiary Assignment*

On an interim basis, CMS is revising the definition of primary care services used in MSSP assignment methodology starting with PY 2020 and for any subsequent performance year that starts during the PHE to recognize virtual check-ins, remote evaluation e-visits, telephone evaluation and management services, and telehealth.



The following will now be included in the definition of primary care services for purposes of beneficiary assignment: HCPCS code G210 (remote evaluation of patient video/images), and HCPCS code 2012 (virtual check-in), CPT codes 99421, 99422, and 99423 (online digital evaluation and management service (e-visit)), and CPT codes 99441, 99442, and 99443 (telephone evaluation and management services).

CMS seeks comment on the revisions to the definition of primary care services including the alternatives considered with regard to adding codes used by non-ACO professionals.

### **Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria**

In the CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies for the Quality Payment Program (QPP) payment year 2022, published in the **Federal Register** on November 15, 2019 (84 FR 62568), CMS finalized that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested prior to submitting the QCDR measure at the time of self-nomination.

However, given the PHE, CMS anticipates that clinicians on the front lines of the COVID-19 pandemic are prioritizing the treatment of COVID-19 patients over QCDR data collection. Additionally, other clinicians working in specialties that *do not* primarily care for COVID-19 patients are canceling or delaying routine visits so that institutional resources may be redistributed to support the treatment of COVID-19 or are under orders to limit in-person visits to emergencies only.

Due to MIPS participants' shift in priorities, CMS expects a reduction in the volume of data collected for testing new measures delaying the QCDR self-nomination by one year (i.e., policies planned to take effect during the 2020 self-nomination period, applicable to the 2021 MIPS program year). As such, CMS is delaying policies requiring QCDRs to submit the information that establishes the quality of the data collected by new measures in advance of the self-nomination period for the MIPS 2022 performance year and measure testing data of all fully formed QCDR measures.

### **Application of Certain National Coverage Determination and Local Coverage Determination Requirements during the PHE for the COVID-19 Pandemic**

#### *Applicability of Reasonable and Necessary Requirement for Covered Items and Services*

External stakeholders questioned whether items and services can be furnished or ordered without reason during the PHE for the COVID-19 pandemic. The Agency has clarified the IFC and section 1135 PHE waiver authority cannot temporarily or permanently waive the reasonable and necessary statutory requirement. Except as expressly permitted by statute, 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).

In the March 31st COVID-19 IFC, CMS finalized on an interim basis that to the extent a national coverage determination (NCD) or local coverage determination (LCD) (including articles) would otherwise require a face-to-face or in-person encounter or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic. Additionally, CMS finalized on an interim basis they will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles), allowing for flexibility for practitioners to care for their patients.

### **Medical Education**

Recognizing the urgency of the PHE, and understanding that hospitals may need additional flexibilities to expand capacity in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, CMS is changing its policies during the PHE for the COVID-19 pandemic so that hospitals, Inpatient Rehabilitation Facilities (IRFs), and inpatient psychiatric facilities (IPFs) do not experience undue reductions in indirect medical education adjustment (IME) or teaching status adjustment payment amounts.

The IME payment formula is determined in part using each teaching hospital's ratio of allowable FTE residents in the numerator and available beds in the denominator. To accommodate the increase in COVID-19-related patients, many hospitals are increasing their number of inpatient beds. Using the exceptions and adjustments authority, and to mitigate IME payment changes from pre-COVID levels, for the duration of the COVID-19 PHE, for purposes of determining a hospital's IME payment amount, the hospital's available bed count is considered to be the same as it was on the day before the COVID-19 PHE was declared. Beds temporarily added during the timeframe of the COVID-19 PHE will be excluded from the calculations to determine IME payment amounts. Therefore, for the duration of the COVID-19 PHE, an IRF's or an IPF's teaching status adjustment payment amount will be the same as it was on the day before the COVID-19 PHE was declared.

Additionally, CMS is revising regulations to allow teaching hospitals during the COVID-19 PHE to claim for purposes of IME and direct Graduate Medical Education (DGME) payments the time spent by residents training at other hospitals. If the teaching hospital to which a resident is assigned sends the resident to another hospital and claims the resident's time, no other hospital, teaching or non-teaching, would be able to claim that time. During the COVID-19 PHE, the presence of residents in non-teaching hospitals will not trigger establishment of per resident amounts or FTE resident caps at those non-teaching hospitals.

### **Additional Flexibility under the Teaching Physician Regulations**

Medicare may make payment under the PFS for teaching physician services when a resident furnishes services permitted under the primary care exception, including via telehealth, and the



teaching physician can provide the necessary direction, management and review of the resident's services using interactive audio/video real-time communications technology. The teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, ensure that the services furnished are appropriate, and review with each resident during or immediately after each visit the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies.

On an interim basis for the duration of the COVID-19 PHE, Medicare may make PFS payment to the teaching physician for the following additional services when furnished by a resident under the primary care exception: Telephone E/M visits, telehealth transitional care management, online E/M services, interprofessional telephone/electronic visits,

Taken together, these policies mean that, on an interim basis for the duration of the PHE for the COVID-19 pandemic, Medicare may make PFS payment for teaching physician services when a resident furnishes a service included in this expanded list of services in primary care centers, including via telehealth, and the teaching physician can provide the necessary direction, management and review for the resident's services using audio/video real-time communications technology. CMS believes that these policies will increase the capacity of teaching settings to respond to the PHE for the COVID-19 pandemic as more practitioners are being asked to assist with the response.

### **Payment for Audio-Only Telephone Evaluation and Management Services**

CMS received responses from providers after the issuance of the first COVID-19 IFC explaining that audio-only services are being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the office/outpatient E/M codes. Therefore, CMS is establishing new RVUs for the telephone E/M services based on crosswalks to the most analogous office/outpatient E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the office/outpatient E/M codes. Specifically, CMS is crosswalking CPT codes 99212, 99213, and 99214 to 99441, 99442, and 99443 respectively. The Agency is finalizing, on an interim basis and for the duration of the COVID-19 PHE the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. It is also finalizing the direct PE inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with CPT code 99213 for CPT code 99442, and the direct PE inputs associated with CPT code 99214 for CPT code 99443. CMS is not finalizing increased payment rates for CPT codes 98966-98968 as these codes describe services furnished by practitioners who cannot independently bill for E/Ms and so these telephone assessment and management services, by definition, are not furnished in lieu of an office/outpatient E/M service.

Additionally, given CMS' understanding that these audio-only services are being furnished as substitutes for office/outpatient E/M services, the Agency recognizes that they should be considered as telehealth services, and are adding them to the list of Medicare telehealth services for the duration of the PHE. CMS will also separately issue a waiver of the requirements that Medicare telehealth services must be furnished using video technology.



Although practitioners have been provided flexibility around cost-sharing for the duration of the PHE, beneficiaries are still liable for cost-sharing for these services in instances where the practitioner does not waive cost-sharing. Practitioners should educate beneficiaries on any applicable cost-sharing. CMS is seeking comment on how best to minimize unexpected cost sharing for beneficiaries.

### **Time Used for Level Selection for Office/Outpatient Evaluation and Management Services Furnished Via Medicare Telehealth**

In the March 31st COVID-19 IFC, for the duration of the PHE for the COVID-19 pandemic, CMS revised its policy to specify that the office/outpatient E/M level selection for office/outpatient E/M services when furnished via telehealth 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. CMS stated that currently there are typical times associated with the office/outpatient E/M visits, and those times are what should be met for purposes of level selection. CMS stated that typical times associated with the office/outpatient E/M visits were available as a public use file at <https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>.

Members of the physician community brought to CMS' attention that the policy announced in the March 31st COVID-19 IFC relies on typical times listed in the public use file even when those times do not align with the typical times included in the office/outpatient E/M code descriptors. CMS agrees that discrepancies between times can be confusing. CMS believes that because the times are being used for the purpose of choosing which level of office/outpatient E/M CPT code to bill, the times listed in the codes themselves would be most appropriate for the purpose. Therefore, CMS is finalizing on an interim basis, for the duration of the PHE for the COVID-19 pandemic, that the typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor.

### **Basic Health Program Blueprint Revisions**

Section 1331 of the Patient Protection and Affordable Care Act<sup>41</sup> provides states with a coverage option, the Basic Health Program (BHP), for specified individuals who do not qualify for Medicaid but whose income does not exceed 200 percent of the federal poverty level (FPL). As of April 2020, Minnesota and New York are the only states operating a BHP.

During the PHE, CMS is revising regulations to allow a state to submit to the Secretary for review and certification a revised Blueprint that makes temporary significant changes to respond to the PHE for the COVID-19 pandemic with the option for the states to make such changes effective retroactive to the start of the PHE for the COVID-19 pandemic. While we would generally expect that revisions submitted during the PHE would no longer be in effect as of the end of the PHE for the COVID-19 pandemic, there may be instances in which policies will need to temporarily be in effect for a longer period of time. For example, following the end of the PHE for the COVID-19 pandemic, a state may need additional time to process all of the renewals



or changes in circumstance that were not completed during the PHE. A state may need an additional, temporary period of time (for example, 90 days), before resuming its usual processing standards. CMS will work with states to determine a reasonable amount of time after the PHE for returning to normal course of business.

### **Payment for Remote Physiologic Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency**

CMS believes that remote physiologic monitoring (RPM) services support the Centers for Disease Control and Prevention's (CDC) goal of reducing human exposure to the novel coronavirus while also increasing access to care and improving patient outcomes. RPM services could allow a patient with an acute respiratory virus to monitor pulse and oxygen saturation levels using pulse oximetry. Nurses or other auxiliary personnel, working with physicians, can check-in with the patient and then using patient data, determine whether home treatment is safe, all the while reducing exposure risk and eliminating potentially unnecessary emergency department and hospital visits.

CMS was notified by stakeholders that CPT coding guidance states that the RPM service described by CPT code 99454 cannot be reported for monitoring of fewer than 16 days during a 30-day period. In reviewing other RPM codes, CMS found that CPT codes 99091, 99453, 99457, and 99458, also have 30-day reporting periods. Stakeholders have alerted CMS that while it is possible that remote physiologic monitoring would be used to monitor a patient with COVID-19 for 16 or more days, many patients with COVID-19 who need monitoring do not need to be monitored for as many as 16 days. For the purposes of treating suspected COVID-19 infections, CMS is establishing a policy on an interim final basis for the duration of the COVID-19 PHE to allow RPM monitoring services to be reported to Medicare for periods of time that are fewer than 16 days of 30 days, but no less than 2 days, as long as the other requirements for billing the code are met.

### **Flexibility for Medicaid Laboratory Services**

CMS is amending §440.30 to permit flexibility for coverage of COVID-19 tests, including coverage for tests administered in non-office settings, and coverage for laboratory processing of self-collected COVID-19 tests that are FDA-authorized for self-collection. The flexibility would apply not only during the current COVID-19 PHE, but also during any subsequent periods of active surveillance, to allow for continued surveillance as part of strategies to detect recurrence of the virus in individuals and populations to prevent further spread of the disease.

CMS defines a period of active surveillance as an outbreak of communicable disease during which no approved treatment or vaccine is widely available. A period of active surveillance ends on the date the Secretary terminates it, or the date that is two incubation periods after the last known case of the communicable disease, whichever is sooner. CMS seek comments on this definition of the period of active surveillance.



States are permitted to cover laboratory processing of self-collected test systems that the FDA has authorized for home use, without the order of a treating physician or other licensed non-physician practitioner (NPP). Laboratories that process such test systems without an order, must notify the patient and the patient's physician or NPP, if known by the laboratory, of the results. The flexibilities that would permit self-collection of testing will apply only for test systems authorized by the FDA for home use. **CMS is soliciting comment on the implications of applying this provision to future public health emergencies, and the specifications that should be included in doing so.** These provisions will ease restrictions under existing law and make Medicaid coverage of testing more available, and will be effective retroactive to March 1, 2020. **CMS is soliciting comment on whether these requirements would present any obstacles to providing Medicaid coverage for COVID-19 testing.**