Laboratories: CMS Flexibilities to Fight COVID-19

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly respond to people impacted by COVID-19. CMS developed a cross-cutting initiative to use a comprehensive, streamlined approach to reestablish certain health and safety standards and other financial and program requirements at the eventual end of the COVID-19 public health emergency.

This CMS cross-cutting initiative focused on evaluating CMS-issued PHE waivers and flexibilities to prepare the health care system for operation after the PHE. This review happened in three concurrent phases:

1. CMS assessed the need for continuing certain waivers based on the current phase of the PHE. Since the beginning of the PHE, CMS has both added and terminated flexibilities and waivers as needed. In doing so, CMS considered the impacts on communities — including underserved communities — and the potential barriers and opportunities that the flexibilities may address.

2. CMS assessed which flexibilities would be most useful in a future PHE, such as natural and man-made disasters and other emergencies, to ensure a rapid response to future emergencies, both locally and nationally, or to address the unique needs of communities that may experience barriers to accessing health care.

3. CMS is continuing to collaborate with federal partners and the health care industry to ensure that the health care system is holistically prepared for addressing future emergencies.

As CMS identified barriers and opportunities for improvement, the needs of each person and community served were considered and assessed with a health equity lens to ensure our analysis, stakeholder engagement, and policy decisions account for health equity impacts on members of underserved communities and health care professionals disproportionately serving these communities.

Please note: This fact sheet focuses on Medicare and Medicaid flexibilities only.

Medicare COVID-19 Diagnostic Testing

- *Price Transparency for COVID-19 Testing:* In an Interim Final Rule with Comment Period (IFC) issued October, 28, 2020, CMS implemented the CARES Act requirement that providers of a diagnostic test for COVID-19 are to make public the cash price for such tests on their websites. Providers without websites have been required to provide price information in writing, within two business days upon request, and on a sign posted

prominently at the location where the provider performs the COVID-19 diagnostic test, if such location is accessible to the public. Noncompliance may result in civil monetary penalties up to $300 per day. **After the PHE, in accordance with the CARES Act, this special price transparency requirement will terminate. Price transparency requirements under other laws and regulations will continue to apply.**

- *Laboratory Specimen Collection from Patient's Home:* During the PHE, Medicare could pay when laboratories send trained technicians to collect a sample from a homebound beneficiary or a non-hospital inpatient for COVID-19 diagnostic testing. Medicare could pay a specimen collection fee and for the travel. During the PHE, the nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally was $23.46 and for individuals in a non-covered stay in a SNF, or whose samples are collected by a laboratory on behalf of an HHA, is $25.46. **These payment amounts, billed with HCPCS codes G2023 and G2024 will end at the termination of the COVID-19 PHE.**

- *Physician or Practitioner Order for COVID-19 tests:* In the COVID-19 Public Health Emergency Interim Final Rule #3 (CMS-3401-IFC), we revised a previous policy that covered multiple COVID-19 tests for an individual beneficiary without a physician or other practitioner order. Medicare has been covering a beneficiary's first COVID-19 test without an order. Subsequent tests require a physician's or other practitioner order. This change has ensured that beneficiaries receive appropriate medical attention if they feel they need multiple tests and has reduced the risk of fraud. FDA requirements for an order and state requirements around ordering diagnostic tests still applied. CMS also removed certain documentation and recordkeeping requirements associated with orders for COVID-19 diagnostic tests as these requirements would not be relevant in the absence of an order. CMS still requires laboratories to furnish the results of COVID-19 tests to the beneficiary. Consistent and regular reporting of all testing results to local officials is critical to public health management of the pandemic, so we would expect any clinician or laboratory receiving results to report those results promptly, consistent with state and local public health requirements, typically within 24 hours. **After the PHE, Medicare will require all COVID-19 and related testing that is performed by a laboratory to be ordered by a physician or non-physician practitioner.**

- *Pharmacists:* A pharmacy that acquires a CLIA certificate can enroll with Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests authorized under their certificate, and many pharmacies have done this to furnish and bill for COVID-19 clinical diagnostic laboratory tests during the PHE. This is permissible under current permanent Medicare policies and remains after the end of the PHE as long as the pharmacy retains its CLIA certification and is enrolled in Medicare as a clinical diagnostic laboratory. In addition, to help ensure that beneficiaries can get the tests they need, CMS covers laboratory-performed COVID-19 and related testing when ordered by a pharmacist or other health care professional permitted by their state to order diagnostic laboratory tests. The interim final rule, in revising previous policy for

the PHE, allowed laboratories to be paid when pharmacists ordered these tests. **This ordering flexibility ends with the end of the PHE. Diagnostic laboratory tests must be ordered by a physician or nonphysician practitioner.**

- *Antibody (serology) tests*: FDA-authorized COVID-19 serology testing is a Medicare-covered diagnostic test for patients with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. The outcome of the serology test may change the health care decisions made by a patient and their practitioner. **At the end of the PHE, coverage is at the Medicare Administrative contractor's discretion.**

- ***Increased payment for COVID-19 laboratory tests performed using high throughput technologies:*** Medicare has paid a higher payment for COVID-19 clinical diagnostic lab tests making use of high-throughput technologies developed by the private sector that allows for increased testing capacity, faster results, and more effective means of combating the spread of the virus. High-throughput lab tests can process more than two hundred specimens a day using highly sophisticated equipment that requires specially trained technicians and more time-intensive processes to assure quality. These increased payments are effective through the end of the PHE. When the COVID-19 PHE ends, payment rates will revert to those rates under the Clinical Laboratory Fee Schedule. HCPCS codes U0003, U0004, and U0005 created for this policy will no longer be payable.

Reducing Administrative Burden

- *"Stark Law" Waivers:* The physician self-referral law (also known as the "Stark Law") 1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and 2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. On March 30, 2020, CMS issued blanket waivers of certain provisions of the Stark Law. These blanket waivers applied to financial relationships and referrals that are related to the COVID-19 emergency. The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 purposes, as defined in the blanket waiver document. During the PHE, CMS permitted certain referrals and the submission of related claims that would otherwise violate the Stark Law, if all requirements of the waivers were met. **When the COVID-19 PHE ends, the waivers will terminate and physicians and entities must immediately comply with all provisions of the Stark Law.**

Flexibilities under the "Stark Law" waivers have included:

- Hospitals and other health care providers could pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties could pay below fair market value to rent equipment or purchase items or services. For example, a physician practice could rent or sell needed equipment to a hospital at a price below what the practice could charge another party. Or, a hospital could provide space on hospital grounds at no charge to a physician who is willing to treat patients who sought care at the hospital but were not appropriate for emergency department or inpatient care.
- Health care providers could support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital could make a personal loan to the hospital without charging interest at a fair market rate so that the hospital could make payroll or pay its vendors.
- Hospitals could provide benefits to their medical staff, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians were at the hospital and engaging in activities that benefited the hospital and its patients.
- Health care providers could offer certain items and services that were solely related to COVID-19 purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap. For example, a home health agency could provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital could provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital's emergency department.
- Physician-owned hospitals could temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital could temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.
- Some of the restrictions regarding when a group practice could furnish medically necessary designated health services (DHS) in a patient's home were loosened. For example, <u>any</u> physician in the group could order medically necessary DHS that were furnished to a patient by one of the group's technicians or nurses in the patient's home contemporaneously with a physician service that was furnished via telehealth by the physician who ordered the DHS.
- Group practices could furnish medically necessary MRIs, CT scans, or clinical laboratory services from locations like mobile vans in parking lots that the group practice rented on a part-time basis.

COVID-19 Accelerated and Advance Payments (CAAP): For the most up to date information related to the CAAP Program, please visit https://www.cms.gov/medicare/covid-19-accelerated-and-advance-payments

- *Provider Enrollment*: During the PHE, CMS has established toll-free hotlines for physicians, non-physician practitioners, and Part A certified providers and suppliers who have established isolation facilities to enroll and receive temporary Medicare billing privileges. **When the PHE ends, the hotlines will be shut down.** Additionally, CMS has provided the following flexibilities for provider enrollment:

  - *Screening requirements:*
    - Site Visits: CMS waived provider enrollment site visits for moderate and high-risk providers/suppliers. ***(This waiver terminated on 07-06-2020, and CMS, in accordance with 42 CFR §§ 424.517 and 424.518, resumed all provider enrollment site visits.)***

    - *Fingerprint-based criminal background checks:* CMS waived the requirement for fingerprint-based criminal background checks for 5% or greater owners of newly enrolling high-risk categories of providers and suppliers (e.g., newly-enrolling Home Health Agencies, DMEPOS suppliers, Medicare Diabetes Prevention Programs, Opioid Treatment Programs). ***(This waiver terminated on 10/31/2021, and CMS, in accordance with 42 CFR § 424.518, resumed requesting fingerprints for all newly enrolling high-risk providers and suppliers.)***

  - *Application Fees:* CMS waived the collection of application fees for institutional providers who are initially enrolling, revalidating, or adding a new practice location. ***(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 CFR § 424.514, resumed collecting application fees.)***

  - *Revalidation:* CMS postponed all revalidation actions. This did not prevent a provider who wanted to submit a revalidation application from doing so; MACs processed revalidation applications. ***(This waiver terminated on 10/31/2021 and CMS resumed a phased-in approach to revalidation activities; revalidation letters began being mailed again in October 2021 with due dates in early 2022.)***

  - *Expedited Enrollment:* CMS expedited any pending or new applications from providers and suppliers, including physicians and non-physician practitioners received on or after March 1, 2020. When the PHE ends, CMS will resume normal application processing times.

  - *Opt-Out Enrollment:* CMS allowed practitioners to cancel their opt-out status early and enroll in Medicare to provide care to more patients. CMS also allowed MACs to

accept opt-out cancellation requests via email, fax, or phone call to the hotline. CMS allowed a provider to submit an application (an 855-I or 855-R, for example) to cancel their opt-out. Providers were not required to submit a written notification to cancel their opt-out status. **When the PHE ends, this waiver will terminate and opted-out practitioners will not be able to cancel their opt-out statuses earlier than the applicable regulation at 42 CFR 405.445 allows for.**

- *Reporting Home Address:* During the PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. **When the PHE ends, practitioners will be required to resume repor**ting their home address on the Medicare enrollment.

- *State Licensure:* During the PHE, CMS allowed licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment. **CMS has determined that when the PHE ends, CMS regulations will continue to allow for a total deferral to state law.** Thus, there is no CMS-based requirement that a provider must be licensed in its state of enrollment.

Medicare appeals in Traditional Medicare, Medicare Advantage (MA) and Part D

- During the PHE, CMS has been allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program (42 CFR 405.942 and 42 CFR 405.962) and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs) (42 CFR 422.582 and 42 CFR 423.582) to allow extensions to file an appeal. Specifically, 42 CFR 422.582(c) and 42 CFR 423.582(c) allow a Part C or Part D plan to extend the timeframe for filing a request if there is good cause for the late filing. In addition, the Part D IRE may find good cause for late filing of a request for reconsideration. When the COVID-19 PHE ends, these flexibilities will continue to apply consistent with existing authority and requests for appeals must meet the existing regulatory requirements.

- During the PHE, CMS has been allowing MACs and QICs in the FFS program (42 CFR 405. 950 and 42 CFR 405.966), and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals**.** In addition, under applicable regulations, MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest (42 CFR 422.568(b)(1)(i), 42 CFR 422.572(b)(1) and 42 CFR 422.590(f)(1)). **When the COVID-19**

PHE ends, these flexibilities will continue to apply consistent with existing authority and requests for appeals must meet the existing regulatory requirements.

- During the PHE, CMS has been allowing MACs and QICs in the FFS program (42 CFR 405.910) and MA and Part D plans, as well as the Part C and Part D IREs, to process an appeal, even with incomplete Appointment of Representation forms (see 42 CFR 422.561 and 42 CFR 423.560 for definitions of "representative"). However, any communication was sent only to the beneficiary. **When the COVID-19 PHE ends, this flexibility will continue to apply, consistent with existing guidance for the MACs and QIC in the FFS program. For MA and Part D plans, as well as the Part C and Part D IREs, this flexibility will no longer apply. The MA and Part D plans, as well as the Part C and D IREs, must process the appeals based on regulatory requirements (42 CFR 422.582(f)-(g), 42 CFR 423.582(e)-(f), 42 CFR 422.592(d)-(e), and 42 CFR 423.600(g)-(h))**.

- During the PHE, CMS has been allowing MACs and QICs in the FFS program (42 CFR 405. 950 and 42 CFR 405.966) and MA and Part D plans, as well as the Part C and Part D IREs, to process requests for appeal that don't meet the required elements, but instead use information that is available (42 CFR 422.562 and 42 CFR 423.562). **When the COVID-19 PHE ends, requests for appeals must meet the existing regulatory requirements.**

- During the PHE, CMS has been allowing MACs and QICs in the FFS program (42 CFR 405. 950 and 42 CFR 405.966) and MA and Part D plans, as well as the Part C and Part D IREs, to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied. **When the PHE ends, these flexibilities may only be provided consistent with existing regulatory authority.**

Clinical Laboratory Improvement Act (CLIA) Guidance

- CMS has exercised enforcement discretion to facilitate pathologists' ability to review pathology slides remotely without the need for a separate CLIA certificate for the remote location. **Enforcement discretion is not contingent on PHE authority;** CMS will continue to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations.

- CMS has expedited CLIA certificate application review and processing to ensure that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible during the public health emergency. **CMS has determined that at the end of the PHE, regulations will allow CMS to continue to allow for expedited lab certification by allowing a Laboratory to begin testing as soon as they receive a CLIA number and pay the laboratory fee.**

- CMS has allowed laboratories within a hospital/university hospital campus to hold a single certificate for the laboratory sites within the same physical location or street

address. **CMS has determined that at the end of the PHE, regulations will allow CMS to continue to allow for labs within a hospital to hold a single certificate for the laboratory sites within the same physical location or street address. This requirement is expressly authorized under the CFR (See 42 CFR 493.35(b), 43(b), 55(b).**

- CMS has clarified that alternate specimen collection devices and media may be used to collect and transport COVID-19 samples. CLIA regulations are not prescriptive about the type of transport device; for example, specimen collection swabs and viral transport media that laboratories use to collect the specimens needed to perform a test. CLIA only requires that the laboratory follow the manufacturer's instructions. If a laboratory modifies the manufacturer's instructions, the laboratory must establish performance specifications and validate the assay prior to performing patient testing. CLIA is not prescriptive as to how the study is performed; the Laboratory Director is responsible for defining the validation parameters. **CMS has determined that at the end of the PHE, regulations will allow CMS to continue to use alternate specimen collection devices and media. Under existing regulations, Laboratories must either follow manufacturer's instructions or establish performance specifications for a modified procedure, as is reflected in 42 CFR 493.1253(b)(2).**

Additional Guidance

- The Interim Final Rules and waivers can be found at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.
- Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency can be found at: https://www.cms.gov/files/document/qso-20-21-clia.pdf-0.