Unwinding of the COVID-19 Public Health Emergency

Questions? Contact Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org

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Billing, Coding, Documentation & Other Payment Policies

"**Medicare Physician Supervision Requirements**: CMS has temporarily modified the regulatory definition of direct supervision, which requires the supervising physician or practitioner to be "immediately available" to furnish assistance and direction during the service, to include **"virtual presence"** of the supervising clinician through the use of real- time audio and video technology. ***This flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends.***"	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"**Medicare Physician Supervision and Auxiliary Personnel**: The physician could have entered into a **contractual arrangement** that meets the definition of auxiliary personnel at 42 CFR § 410.26, including with staff of another provider/supplier types, such as a home health agency (defined under § 1861(o) of the Act) or a qualified home infusion therapy supplier (defined under § 1861(iii)(3)(D)), or entities that furnish ambulance services, which can provide the staff and technology necessary to provide care that, ordinarily, would have been provided incident to a physician's service (including services that are allowed to be performed via telehealth). In such instances, **the provider/supplier would have sought payment for any services provided by auxiliary personnel from the billing practitioner and would not have submitted claims to Medicare for such services.**	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

• **Obtaining Beneficiary Consent**: During the PHE, **informed consent** to receive services furnished by auxiliary personnel, including for example CCM services, must have been obtained prior to the start of the service. Consent has not had to be obtained at the required initiating visit for CCM that must be performed by the billing practitioner, but it could have been obtained at that time. Since the billing practitioner discusses CCM with the beneficiary during the initiating visit, if consent has been separately obtained, it may have been obtained under general supervision and could have been verbal if it was documented in the medical record and included notification of the required information. Further, there need not be an employment relationship between the person obtaining the consent and the billing practitioner. ***This flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends.***"	

Telehealth & Remote Service Flexibilities

"During the PHE, the Secretary has been using the waiver authority under section 1135 of the Act to create flexibilities in the requirements of section 1834(m) of the Act and 42 CFR § 410.78 for **use of interactive telecommunications systems to furnish telehealth services**. This allows clinicians to furnish more services to beneficiaries via telehealth so that they can take care of their patients while mitigating the risk of the spread of the virus. During the public health emergency, all beneficiaries across the country have been able to receive Medicare telehealth and other communications technology-based services wherever they are located. Additionally, ***after the PHE ends, the Consolidated Appropriations Act, 2023 provides for an extension for some of these flexibilities through December 31, 2024***. CMS has also been using these section 1135 waivers to create further PHE flexibilities to the requirements of section 1834(m)(1) of the Act and 42 CFR § 410.78(a)(3) for the use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of **audio-only equipment** to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services. Unless provided otherwise, other services included on the Medicare Telehealth Services List must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site. Additionally, ***after the PHE ends, the Consolidated Appropriations Act, 2023 extends availability of the telehealth services that can be furnished using audio-only technology through December 31, 2024***. In the CY 2022 Physician Fee Schedule Rule, CMS revised the regulation at 42 CFR § 410.78(a)(3) to permit the **use of audio-only equipment for telehealth services furnished to patients in their homes** under certain circumstances for purposes of diagnosis, evaluation, or treatment of a mental health disorder (including substance use disorder). CMS has waived the requirements of section 1834(m)(4)(E) of the Act	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

and 42 CFR § 410.78 (b)(2), which specify the **types of practitioners** who may bill for their services when furnished as Medicare telehealth services from a distant site. The waiver of these requirements expands the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services. As a result, a broader range of practitioners, such as physical therapists, occupational therapists, and speech language pathologists can use telehealth to provide many Medicare services. ***After the PHE ends, the Consolidated Appropriations Act, 2023 provides for an extension for this flexibility through December 31, 2024***."	
"Medicare pays for **e-visits**, which are brief communication services with practitioners, professionals, clinicians, and providers via a number of communication technology modalities, including synchronous discussion over a telephone or exchange of information through video or image. During the PHE, clinicians can provide remote evaluation of patient video/images and virtual check-in services (HCPCS codes G2010 and G2012 for physicians and G2251 and G2252 are for non-physician practitioners) to both new and established patients. ***After the end of the PHE, these services may only be provided to established patients***." **Code Descriptor References:** • **HCPCS G2010** (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*) • **HCPCS G2012** (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*) • **HCPCS G2250** (*Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.)* • **HCPCS G2251** (*Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion).*	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf#page=7

Permanent Medicare change • Rural hospital emergency departments are accepted as an originating site. **Temporary Medicare changes ending 12/31/24** • Federally Qualified Health Center (FQHC)/Rural Health Clinic (RHC) can serve as a distant site provider for non-behavioral/mental telehealth services. • Medicare patients can receive telehealth services authorized in the Calendar Year 2023 Medicare Physician Fee Schedule in their home. • Some non-behavioral/mental telehealth services can be delivered using audio-only communication platforms. **Temporary changes through the end of the COVID-19 public health emergency** • Telehealth can be provided as an excepted benefit. • Medicare-covered providers may use any non-public facing application to communicate with patients without risking any federal penalties — even if the application isn't in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).	**SOURCE**: https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency
Flexibilities offered through the OIG Telehealth Policy will end May 11, 2023.	**SOURCE**: https://oig.hhs.gov/coronavirus/covid-flex-expiration.asp

COVID-19 Testing, Vaccination, and Treatment

Testing

"**Coverage for COVID-19 testing for Americans will change**. Medicare beneficiaries who are enrolled in Part B will continue to have coverage without cost sharing for laboratory-conducted COVID-19 tests when ordered by a provider, but their current access to free over-the-counter (OTC) COVID-19 tests will end, consistent with the statute on Medicare payment for OTC tests set by Congress. The ***requirement for private insurance companies to cover COVID-19 tests without cost sharing, both for OTC and laboratory tests, will end*.** However, coverage may continue if plans choose to continue to include it. We are encouraging private insurers to continue to provide such coverage going forward. **State Medicaid programs must provide coverage without cost sharing for COVID-19 testing until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 PHE**. That means with the COVID-19 PHE ending on May 11, 2023, this ***mandatory coverage will end on September 30, 2024, after which coverage may vary by state.***	**SOURCE:** https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html

Additionally, dependent on supply and resources, the **USG may continue to distribute free COVID-19 tests from the Strategic National Stockpile through the United States Postal Service, states, and other community partners.** Pending resource availability, the Centers for Disease Control and Prevention's (CDC) Increasing Community Access to Testing (ICATT) program will continue working to ensure continued equitable access to testing for uninsured individuals and areas of high social vulnerability through pharmacies and community-based sites."	
"On April 4, 2022, **Medicare implemented a demonstration program to allow people with Medicare to receive up to eight tests per calendar month at no cost**. This is the first time that Medicare has covered an over-the-counter, self-administered, test. This new initiative enables people with Medicare Part B, including those enrolled in a Medicare Advantage plan, to receive tests at no cost from providers and suppliers who are eligible to participate. Pharmacies and other health care providers interested in participating in this initiative can get more information. ***This program will end at the end of the COVID-19 public health emergency.***"	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"**COVID-19 Diagnostic Testing**: During the PHE, CMS specified that the **level one E/M visit** (CPT code 99211), which can ordinarily be billed only when clinical staff perform services incident to the services of the billing physician or practitioner for an established patient, can be billed when clinical staff assess a patient and collect a specimen for a COVID-19 diagnostic test for both new and established patients. ***After the PHE, the usual requirements for billing the level 1 E/M visit (CPT code 99211) apply***."	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"**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's 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***."	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

Vaccination & Treatment

"**Access to COVID-19 vaccinations and certain treatments, such as Paxlovid and Lagevrio, will generally not be affected.** To help keep communities safe from COVID-19, HHS remains committed to maximizing continued access to COVID-19 vaccines and treatments. Partners across the U.S. Government (USG) are developing plans to ensure a smooth transition for the provision of COVID-19 vaccines and treatments as part of the traditional health care marketplace and are committed to executing this transition in a thoughtful, well-coordinated manner. Importantly, this transition to more traditional health care coverage is not tied to the ending of the COVID-19 PHE and in part reflects the fact that the federal government has not received additional funds from Congress to continue to purchase more vaccines and treatments. When this transition to traditional health care coverage occurs later this year, many Americans will continue to pay nothing out-of-pocket for the COVID-19 vaccine. **Vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are a preventive health service for most private insurance plans and will be fully covered without a co-pay.** Currently, *COVID-19 vaccinations are covered under Medicare Part B without cost sharing, and this will continue.* ***Medicaid will continue to cover all COVID-19 vaccinations without a co-pay or cost sharing through September 30, 2024, and will cover ACIP-recommended vaccines for most beneficiaries thereafter****.* **Out-of-pocket expenses for certain treatments may change**, depending on an individual's health care coverage, similar to costs that one may experience for other drugs through traditional coverage. ***Medicaid programs will continue to cover COVID-19 treatments without cost sharing through September 30, 2024. After that, coverage and cost sharing may vary by state***."	**SOURCE:** https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html
"On October 28, 2020, CMS released an Interim Final Rule with comment period (IFC) announcing that **Medicare Part B would establish coding and payment rates for COVID-19 vaccines and their administration as preventive vaccines, without cost-sharing, as soon as the Food and Drug Administration (FDA) authorized or approved the product through an Emergency Use Authorization (EUA) or Biologics License Application (BLA).** The IFC also implemented provisions of the CARES Act to ensure swift **coverage of COVID-19 vaccines by private health insurance plans participating in the Health Insurance Marketplace, without cost sharing, from both in- and out-of-network providers, during the course of the public health emergency (PHE).**"	**SOURCE:** https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"**CMS will continue to pay approximately $40 per dose for administering COVID-19 vaccines in most outpatient settings for Medicare beneficiaries through the end of the calendar year in which the**	**SOURCE**: https://www.cms.gov/files/document/physicians-

Secretary ends the EUA declaration for drugs and biologicals with respect to COVID- 19. The EUA declaration is distinct from, and not dependent on, the PHE for COVID-19. **Effective January 1 of the year following the year in which the EUA declaration ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Medicare Part B preventive vaccines, that is, approximately $30 per dose**."	and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"In calendar year 2023, **CMS will pay approximately $36 in addition to the standard administration amount (approximately $40 per dose) to administer COVID-19 vaccines in the home for certain Medicare patients.** For vaccines requiring multiple doses, this payment **applies for each dose in the series**, including any additional or booster doses. We also geographically adjust the additional amount and administration rate based on where you administer the vaccine. **Starting January 1, 2023, we'll also annually update the additional in-home payment rate for administering the COVID-19 vaccine to reflect changes in costs related to administering preventive vaccines.**"	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"[CMS will] **continue to pay a total payment of approximately $76 per dose to administer COVID-19 vaccines in the home for certain Medicare patients through calendar year 2023**. ***The additional payment is not affected by the end of the PHE***."	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"There are currently no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States. The FDA issued emergency use authorizations (EUA) for monoclonal antibody therapies used for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. The FDA also issued an EUA for a monoclonal antibody product used as a pre-exposure prophylaxis of COVID-19 in adults and pediatric patients with certain conditions. **During the EUA declaration for drugs and biologicals with respect to COVID-19, CMS covers and pays for these infusions or injections the same way it covers and pays for COVID-19 vaccines when furnished consistent with the EUA. There's also no beneficiary cost sharing and no deductible for COVID-19 monoclonal antibody products when providers administer them. In the event these products become approved or authorized for use, they will continue to be covered and paid under the Medicare Part B preventive vaccine benefit until the end of the calendar year in which the Secretary ends the EUA declaration. This coverage and payment will continue even after the PHE ends.**	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

CMS doesn't pay for the COVID-19 monoclonal antibody product when a health care setting has received it for free. If a health care setting purchased the product from the manufacturer, Medicare pays the reasonable cost or 95% of the average wholesale price."	
"***Effective January 1 of the year following the year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19, CMS will pay for monoclonal antibodies used for the treatment or for post-exposure prophylaxis of COVID-19:*** • ***As we pay for biological products under Section 1847A of the Social Security Act.*** • ***Through the applicable payment system, using the appropriate coding and payment rates, similar to the way we pay for administering other complex biological products.*** Monoclonal antibodies that are used for pre-exposure prophylaxis prevention of COVID-19 will continue to be paid under the Part B preventive vaccine benefit if they meet applicable coverage requirements."	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"**Oral antivirals that are procured by the U.S. government (USG) and provided to pharmacies are provided to patients at no cost. This process will continue while oral antivirals are being procured by the USG.** The FDA issued an emergency use authorization (EUA) for oral antivirals for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients."	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"**Oral antivirals for COVID-19** that otherwise meet the statutory requirements for Part D coverage at section 1860D-2(e) of the Social Security Act and are not procured by the US government **must be covered by Part D plans, as a formulary product or through the formulary exception process**. This applies to oral antivirals for COVID-19 with emergency use authorization (EUA) under section 564 of the Federal Food, Drug and Cosmetic Act through December 31, 2024, consistent with Section 4131 of the Consolidated Appropriations Act,2023 and any such products that receive FDA approval."	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf
"As of April 25, 2022, **VEKLURYTM (remdesivir) is approved for the treatment of COVID-19**. The federal government didn't purchase a supply of remdesivir. **Medicare Part B provides payment for the drug and its administration under the applicable Medicare Part B payment policy when a facility or practitioner provides it in the outpatient setting,** according to the FDA approval. In most cases, the Medicare patient's yearly Part B deductible and 20% co-insurance apply."	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf

Medicaid Coverage

"**The process for states to begin eligibility redeterminations for Medicaid will not be affected**. During the COVID-19 PHE, Congress has provided critical support to state Medicaid programs by substantially increasing the federal matching dollars they receive, as long as they agreed to important conditions that protected tens of millions of Medicaid beneficiaries, including the condition to maintain Medicaid enrollment for beneficiaries until the last day of the month in which the PHE ends. However, ***as part of the Consolidated Appropriations Act, 2023 Congress agreed to end this condition on March 31, 2023, independent of the duration of the COVID-19 PHE.***"	**SOURCE:** https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html
"The expiration of the **continuous coverage** requirement authorized by the Families First Coronavirus Response Act (FFCRA) presents the single largest health coverage transition event since the first open enrollment period of the Affordable Care Act. As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, states have been required to maintain enrollment of nearly all Medicaid enrollees. When the continuous coverage requirement expires, **states will have up to 12 months to return to normal eligibility and enrollment operations.** Additionally, **many other temporary authorities adopted by states during the COVID-19 public health emergency (PHE), including Section 1135 waivers and disaster relief state plan amendments (SPAs), will expire at the end of the PHE, and states will need to plan for a return to regular operations across their programs.** CMS will continue to update this page as additional tools and resources are released."	**SOURCE**: https://www.medicaid.gov/resources-for-states/coronavirus-disease-2019-covid-19/unwinding-and-returning-regular-operations-after-covid-19/index.html
Anticipated 2023 State Timelines for Initiating Unwinding-Related Renewals As of February 24, 2023	**SOURCE:** https://www.medicaid.gov/resources-for-states/downloads/ant-2023-time-init-unwin-reltd-ren-02242023.pdf
10 Things to Know About the Unwinding of the Medicaid Continuous Enrollment Provision	Kaiser Family Foundation
Medicaid's Response to COVID-19	Medicaid and CHIP Payment and Access Commission (MACPAC)

See: State Medicaid Agency websites.

Alabama	Hawaii	Massachusetts	New Mexico	South Dakota
Alaska	Idaho	Michigan	New York	Tennessee
Arizona	Illinois	Minnesota	North Carolina	Texas
Arkansas	Indiana	Mississippi	North Dakota	Utah
California	Iowa	Missouri	Ohio	Vermont
Colorado	Kansas	Montana	Oklahoma	Virginia

Connecticut	Kentucky	Nebraska	Oregon	Washington
Delaware	Louisiana	Nevada	Pennsylvania	West Virginia
Florida	Maine	New Hampshire	Rhode Island	Wisconsin
Georgia	Maryland	New Jersey	South Carolina	Wyoming

See: Territory Medicaid Agency websites

American Samoa Medicaid Office: 648-699-4777	District of Columbia	Guam	Northern Mariana Islands	Puerto Rico	US Virgin Islands

COVID-19 Reporting Requirements

"**Reporting of COVID-19 laboratory results and immunization data to CDC will change**. CDC COVID-19 data surveillance has been a cornerstone of our response, and during the PHE, HHS has had the authority to **require lab test reporting for COVID-19**. **At the end of the COVID-19 PHE, HHS will no longer have this express authority to require this data from labs, which may affect the reporting of negative test results and impact the ability to calculate percent positivity for COVID-19 tests in some jurisdictions**. CDC has been working to sign voluntary Data Use Agreements (DUAs), encouraging states and jurisdictions to continue sharing vaccine administration data beyond the PHE. Additionally, **hospital data reporting will continue as required by the CMS conditions of participation through April 30, 2024, but reporting may be reduced from the current daily reporting to a lesser frequency**."	**SOURCE:** https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html

Other Noteworthy Changes

"**Hospital Services**: **CMS has waived requirements at § 482.12(c)(1)-(2) and (4) that Medicare patients in the hospital must be under the care of a physician**. This has allowed hospitals to use other practitioners, such as physician assistants and nurse practitioners, to the fullest extent possible. ***This waiver is required to be implemented in accordance with a state's emergency preparedness or pandemic plan and will expire at the end of the COVID-19 public health emergency.***"	**SOURCE**: https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf