

# Prior COVID-19 Government, Reimbursement & Regulatory Updates

**\*Important Note\*** The content below is no longer being updated but was accurate at the time of posting. ASCO is maintaining member access to this document for historical reference purposes only. For current information please see <https://www.asco.org/covid-resources/govt-reimbursement-regulatory-updates>.

## COVID-19 “Relief Package” Signed into Law March 11, 2021

President Biden signed the \$1.9 trillion American Rescue Package into law on March 11, 2021. Please check [ASCO in Action](#) for details on the provisions impacting providers and patient care.

## Financial Assistance for Providers During COVID-19

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) into law. The law, which established new stimulus and aid programs, will provide more than \$2 trillion in emergency economic relief to individuals and businesses affected by the coronavirus crisis through numerous federal agencies. ASCO is providing this [resource guide](#) to assist members in accessing critical support needed to sustain the care of patients with cancer.

This information is subject to change as federal agencies continue to update and provide clarifying guidance on these programs, and as new legislation is enacted by Congress and the White House. Decisions about which option(s) to pursue will depend on your individual practice situation. ASCO recommends that you consult with your financial advisor about the options outlined in the guide.

## CMS Resources, Highlights, and Updates

Four coronavirus-related relief bills were passed in quick succession in March and April of 2020 with many provisions aimed at assisting providers and hospitals with additional flexibilities and financial relief. On June 23, 2020, CMS issued [FAQs](#) on the *Families First Coronavirus Response Act*, the *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, and other health coverage issues related to COVID-19 (Part 43). The FAQs were prepared jointly by the Department of Labor (DOL), the Department of Health and Human Services (HHS), and the Department of the Treasury.

Previously issued FAQs are available [here](#) and [here](#).

On January 11, 2021, CMS [announced](#) a new web-based platform to help standardize Public Health Emergency (PHE)-related inquiries and Section 1135 waiver requests to the agency. Inquiries may be submitted at any time for an array of qualifying emergencies and use of the site is now required for all inquiries, with very limited exceptions. CMS released companion “Quick Reference Guides” on submitting a [PHE-related inquiry](#) or [requesting a Section 1135 waiver](#).

You can submit an inquiry [here](#). More information on waivers and flexibilities is available from CMS [here](#).

CMS also maintains a set of COVID-19 [toolkits](#) for different populations, including one for [providers](#). This toolkit, last updated August 18, 2021, includes information on:

- How health care providers can enroll in Medicare to bill for administering COVID-19 vaccines
- The COVID-19 Vaccine Medicare coding structure
- The Medicare reimbursement strategy for COVID-19 vaccine administration
- How health care providers can bill correctly for administering vaccines, including roster and centralized billing
- Monoclonal antibody infusion for treating COVID-19
- New COVID-19 Treatments Add-on Payment (NCTAP)

Following is a summary of important HHS actions and announcements related to patient care and coverage at this time.

### **COVID-19 Vaccines Additional Doses**

Effective August 12, 2021, CMS will pay to administer additional doses of COVID-19 vaccines consistent with the FDA EUAs, using CPT code 0003A for the Pfizer vaccine and CPT code 0013A for the Moderna vaccine. Reimbursement will be approximately \$40, the same as other doses of the COVID-19 vaccine.

### **HRSA COVID-19 Coverage Assistance Fund (May 3, 2021)**

On May 3, HHS, through the Health Resources and Services Administration (HRSA), announced the HRSA COVID-19 Coverage Assistance Fund (CAF). This program covers the cost of administering COVID-19 vaccines to patients enrolled in health plans that either do not cover vaccination fees or cover them with patient cost-sharing. As providers cannot bill patients for COVID-19 vaccination fees, this new program addresses an outstanding compensation need for providers on the front lines vaccinating underinsured patients.

For more information, see the [press release](#), [fact sheet](#), [FAQs](#), or visit the [HRSA CAF webpage](#).

### **HHS Expands Pool of Professionals Eligible to Administer COVID-19 Vaccines**

On January 28, 2021, HHS added additional categories of qualified persons authorized to prescribe, dispense, and administer COVID-19 vaccines authorized by the FDA. This action authorizes any healthcare provider who is licensed or certified in a state to prescribe, dispense, and/or administer COVID-19 vaccines in any other state or US territory. It also authorizes any physician, registered nurse, or practical nurse whose license or certification expired within the past five years to prescribe, dispense and/or administer COVID-19 vaccines in any state or US territory so long as the license or certification was active and in good standing prior to the date it went inactive.

Please see this [announcement](#) for additional information, including training requirements and details on liability protections.

### **Access to COVID-19 Vaccines for People with Disabilities and Older Adults: New Legal Guidance and Resources**

On April 13, the Office for Civil Rights (OCR), the Administration for Community Living (ACL), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS) published several new resources to help states, vaccination providers, and others leading COVID-19 response activities improve access to vaccines for people with disabilities and older adults. These resources clarify legal requirements and provide strategies to ensure accessibility.

Please see the [news release](#) from HHS to access these resources from OCR, ACL, and ASPE.

### **Flexibilities for the Oncology Care Model, Other Innovation Center Models**

On June 3, 2020, CMS announced new flexibilities for a number of its Innovation Center models, including the Oncology Care Model (OCM). For the OCM, options include forgoing or adjustment of financial risk, changes to quality reporting, and an extension of the model timeline for one year through June 2022.

For more information and details on changes to affected Innovation Models, including the OCM, see this new [resource](#) from CMS.

## **CARES Provider Relief Fund (PRF): Disbursements, Payment Portal, and Required Attestations & Reporting**

**Applications for Phase 4 funding are now closed. The last date to apply was October 26, 2021.**

**Phase 4 PRF Distribution and ARP Funds** On September 10, 2021, the Administration announced that the U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), is making \$25.5 billion in new funding available for health care providers affected by the COVID-19 pandemic. This includes \$17 billion for Provider Relief Fund (PRF) Phase 4 for a broad range of providers who can document revenue loss and expenses associated with the pandemic and an additional \$8.5 billion in American Rescue Plan (ARP) resources for providers who serve rural Medicaid, Children's Health Insurance Program (CHIP), or Medicare patients.

*Provider [applications](#) opened on September 29, 2021 and closed on October 26, 2021.* HRSA will use existing Medicaid/CHIP and Medicare claims data in calculating portions of these payments. Providers may visit this HRSA [web page](#) for archival information about eligibility requirements, the documents and information providers needed to complete their application, and the application process for PRF Phase 4 and ARP Rural payments. HRSA also updated its [FAQs](#) to reflect the addition of Phase 4 on September 29, 2021.

*Phase 4 General Distribution.* Distribution of \$17 billion will be based on providers' lost revenues and changes in operating expenses *from July 1, 2020, to March 31, 2021.* HRSA will reimburse a higher percentage of lost revenues and expenses for smaller providers as compared to larger providers and provide "bonus" payments based on the amount of services provided to Medicaid, CHIP, and Medicare patients, priced at the generally higher Medicare rates.

75% of the Phase 4 allocation will be calculated based on revenue losses and COVID-related expenses.

Large providers will receive a minimum payment amount that is based on a percentage of their lost revenues and COVID-related expenses; medium and small providers will receive a base payment plus a supplement, with small providers receiving the highest supplement.

HHS will determine the exact amount of the base payments and supplements after analyzing data from all the applications received to ensure the agency stays within its budget and funds are distributed equitably. No provider will receive a Phase 4 payment that exceeds 100% of their losses and expenses.

25% of the Phase 4 allocation will be put towards bonus payments that are based on the amount and type of services provided to Medicaid, CHIP, and Medicare patients. HHS will price Medicaid and CHIP claims data at Medicare rates, with some limited exceptions for some services provided predominantly in Medicaid and CHIP. Providers who serve any patients living in Federal Office of Rural Health Policy-defined rural areas with Medicaid, CHIP, or Medicare coverage, and who otherwise meet the eligibility criteria, will receive a minimum payment.

*American Rescue Plan (ARP) Rural.* Distribution of \$8.5 billion will be based on the amount of services providers furnish to Medicaid/CHIP and Medicare beneficiaries living in Federal Office of Rural Health Policy (FORHP)-defined rural areas. HRSA will price payments at the generally higher Medicare rates for Medicaid/CHIP patients.

ARP Rural is intended to help address the disproportionate impact that COVID-19 has had on rural communities and rural health care providers, and funding will be available to providers who serve patients in these communities. ARP Rural payments are administered jointly with the Provider Relief Fund, and eligible applicants can apply through the same Application and Attestation Portal that will be available to apply for the Phase 4 General Distribution. Eligible rural providers can simultaneously be considered for both Phase 4 and ARP Rural payments.

The [Rural Health Grants Eligibility Analyzer](#) indicates which areas qualify as "rural" for the ARP rural payments.

**\*Update September 16: 60-Day Grace Period for PRF Reporting\*** HHS also announced a final 60-day grace period to help providers come into compliance with their [PRF reporting requirements](#) if they fail to meet the deadline on September 30, 2021, for the first PRF Reporting Time Period. While the deadlines to use funds and the Reporting Time Period will not change, HHS will not initiate collection activities or similar enforcement actions for noncompliant providers during this grace period.

**\*Update September 30: Phase 3 Reconsiderations\*** HHS has released detailed [information](#) about the methodology utilized to calculate Phase 3 payments. Providers who believe their Phase 3 payment was not calculated correctly according to this methodology can [request](#) a reconsideration. Applications are due by November 12, 2021. HRSA has provided details on this process on its [website](#).

**On June 11, 2021**, the U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA) released [revised reporting requirements for recipients of Provider Relief Fund \(PRF\) payments](#). Updates include expanding the amount of time providers will have to report information, efforts to reduce burdens on smaller providers, and extending key deadlines for expending PRF payments for recipients who received payments after June 30, 2020.

The revised reporting requirements will be applicable to providers who received one or more payments exceeding, in the aggregate, \$10,000 during a single Payment Received Period from the PRF General Distributions, Targeted Distributions, and/or Skilled Nursing Facility and Nursing Home Infection Control Distributions. Such providers are required to report in each applicable Reporting Time Period. Reporting must be completed and submitted to HRSA by the last date of the reporting time period. PRF recipients that do not report within the respective reporting time period are out of compliance with payment Terms and Conditions and may be subject to recoupment.

On June 30, 2021, HRSA released updated portal user guides on [registration](#) and [reporting](#). Data entry [worksheets](#) are also now available.

HHS began issuing notices on post-payment reporting requirements in July 2020. On January 15, 2021, HHS issued updated [requirements](#) to reflect language in the Coronavirus Response and Relief Supplemental Appropriations Act of 2021 and opened registration for the reporting portal. The revised reporting requirements supplanting the January 15th requirements can be found [here](#). (This document also supersedes the earlier Post-Payment Notices of Reporting Requirements from [October 2020](#), and [September 2020](#).)

Key updates include:

- The period of availability of funds is based on the date the payment is received (rather than requiring all payments be used by June 30, 2021, regardless of when they were received).
- Recipients are required to report for each Payment Received Period in which they received one or more payments exceeding, in the aggregate, \$10,000 (rather than \$10,000 cumulatively across all PRF payments).
- Recipients will have a 90-day period to complete reporting (rather than a 30-day reporting period).
- The reporting requirements are now applicable to recipients of the Skilled Nursing Facility and Nursing Home Infection Control Distribution in addition to General and other Targeted Distributions.

HRSA has provided the below summary of reporting requirements:

Payment Received Period*		Deadline to Use Funds	Reporting Time Period
Period 1	April 10, 2020 to June 30, 2020	June 30, 2021	July 1 to September 30, 2021
Period 2	July 1, 2020 to December 31, 2020	December 31, 2021	January 1 to March 31, 2022
Period 3	January 1, 2021 to June 30, 2021	June 30, 2022	July 1 to September 30, 2022
Period 4	July 1, 2021 to December 31, 2021	December 31, 2022	January 1 to March 31, 2023

\*Payments exceeding \$10,000 in aggregate received

The PRF Reporting Portal opened for providers to start submitting information on July 1, 2021.

HRSA continues to encourage providers to establish their PRF Reporting Portal accounts now by [registering on HRSA's website](#). Registration will also allow providers to receive updates closer to the official opening of the portal for their reporting submissions.

These reporting requirements are comprehensive and detailed. It is important that providers review them in full to understand their reporting obligations and meet the deadlines set by HHS for reporting. For additional information see the HHS webpage on [Reporting Requirements and Auditing](#) and these associated [FAQs](#). Additional “trending” [FAQs](#) (last updated July 1, 2021) are also available, as is a [compilation](#) of CARES Act PRF FAQs (last updated July 1, 2021).

**Update December 16, 2020: Distribution of \$24 Billion in Phase 3 Provider Relief Funding.** HRSA [announced](#) it has completed review of Phase 3 applications from the PRF program and will distribute \$24.5 billion to over 70,000 providers. Payments to Phase 3 applicants will begin on December 16, 2020.

Phase 3 was originally allocated at \$20 billion, but the addition of another \$4.5 billion in funding is being used to satisfy close to 90 percent of each applicant’s reported lost revenues and net change in expenses caused by the coronavirus pandemic in the first half of 2020.

CARES Act PRF FAQs from HHS are available [here](#) and [here](#). HHS has also published a [state-by-state listing](#) of targeted payments to safety net hospitals through the Provider Relief Fund and a [listing](#) of PRF distributions to providers that have accepted the Terms and Conditions.

**On December 11, 2020**, HRSA posted a PRF [Allowable Expenses Overview](#). The overview is intended to clarify the intent and provide examples of allowable expenses for the use of PRF General and Targeted Distribution payments. It is not an exhaustive list of allowable expenses.

**Updated March 5, 2021: COVID-19 FAQs on Medicare Fee-for-Service Billing.** On August 26, 2020, CMS released a list of [FAQs](#) to Medicare providers regarding the HHS PRF and the Small Business Administration's Paycheck Protection Program payments, also referred to as COVID-19 relief payments. The FAQs provide guidance to providers on how to report provider relief fund payments, uninsured charges reimbursed through the Uninsured Program administered by Health Resources and Services Administration, and Small Business Administration (SBA) Loan Forgiveness amounts. The FAQs also address that provider relief fund payments should not offset expenses on the Medicare Cost Report.

**Important Note: Tax Treatment of Provider Relief Funds.** According to [IRS FAQs](#), a health care provider that receives a payment from the PRF *may not* exclude this payment from gross income as a qualified disaster relief payment under section 139 of the Internal Revenue Code. A payment to a business, even if the business is a sole proprietorship, does not qualify as a qualified disaster relief payment under section 139. The payment from the Provider Relief Fund is includible in gross income under section 61 of the Code.

The IRS also states that, in general, a tax-exempt health care provider that is described in section 501(c) of the Code generally is exempt from federal income taxation under section 501(a). Nonetheless, a payment received by a tax-exempt health care provider from the Provider Relief Fund may be subject to tax under section 511 if the payment reimburses the provider for expenses or lost revenue attributable to an unrelated trade or business as defined in section 513.

**Attestation.** The deadline for health care providers to attest to receipt of payments from the PRF and accept the Terms and Conditions was [extended](#) for a second time on May 22 to a total of 90 days, increased from the original 30 days. The text below has been updated to reflect this extension.

#### *First General Allocation Disbursement (\$30B)*

On April 16, CMS opened its ["CARES Provider Relief Fund" payment portal](#). Recipients of the payments from the first \$30 billion disbursement (based on Medicare FFS billing and deposited automatically into accounts associated with TINs) must sign an attestation through this portal confirming receipt of the funds and agree to the [terms and conditions \(T&Cs\)](#) within 90 days of payment. Recipients who choose to reject the funds must also complete the attestation to indicate fund rejection; not returning the funds within 90 days will be viewed as acceptance of the terms and conditions.

Providers are encouraged to carefully review the T&Cs in full prior to attestation. Requirements include, but are not limited to, the following:

- Payment will only be used to prevent, prepare for, and respond to coronavirus, and shall reimburse the recipient only for health care related expenses or lost revenues that are attributable to coronavirus
- For all care for a possible or actual case of COVID-19, recipient certifies that it will not seek to collect from the patient out-of-pocket expenses in an amount greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network recipient
- Not later than 10 days after the end of each calendar quarter, any recipient that is an entity receiving more than \$150,000 total in funds under the CARES Act and related Acts shall submit

to the Secretary and the Pandemic Response Accountability Committee a detailed report of how funds were expended or obligated

- The recipient must maintain appropriate records and cost documentation and other information required by future program instructions to substantiate the reimbursement of costs under this award, and shall submit reports as the Secretary determines are needed

HHS partnered with UnitedHealth Group (UHG) to deliver the stimulus payments, and physicians should contact UHG's Provider Relations at **866-569-3522** about eligibility, whether a payment has been issued, and where it was sent. If a physician or practice did not already set up direct deposit through CMS or UHG's Optum Pay, they will receive a check at a later date. Practices that would like to set up direct deposit now can call the UHG Provider Relations number.

#### *Second General Allocation Disbursement (\$20B)*

On April 22, HHS [announced](#) that an additional \$20 billion will be available for Medicare providers and facilities as part of the "General Allocation" fund. Funds will be based on 2018 net patient revenue, not just Medicare Fee for Service. On April 24, a portion of providers were automatically sent an advance payment based on the revenue data they submitted in CMS cost reports. Providers without adequate cost report data on file will need to submit their revenue information to the new [portal](#) for distribution of these funds. Providers who receive funds automatically will still need to submit revenue information for verification. Like the distribution of the initial \$30 billion, providers must confirm receipt of funds and agree to the terms and conditions within 90 days.

For a more detailed description of the second general allocation disbursement (\$20B) and of the full \$40.4B distributed in this second round (\$20B in general allocation, \$20.4B in targeted allocation), please see ASCO's [HHS Provider Relief Fund Guide](#) and [HHS' CARES Act Provider Relief Fund General Distribution FAQs](#).

#### *Allocation to Medicaid and CHIP Providers, Safety Net Hospitals and "Hotspots" (\$25B)*

On June 9, 2020, HHS (through HRSA), [announced](#) additional distributions to eligible Medicaid and Children's Health Insurance Program (CHIP) providers that participate in state Medicaid and CHIP programs.

**Medicaid and CHIP Providers (\$15B).** On June 10, 2020, HHS launched an enhanced PRF Payment Portal that will allow eligible Medicaid and CHIP providers to report their annual patient revenue, which will be used as a factor in determining their PRF payment. The payment to each provider will be at least 2% of reported gross revenue from patient care; the final amount each provider receives will be determined after the data is submitted, including information about the number of Medicaid patients that providers serve.

To be eligible for this funding, health care providers ***must not have received payments from the \$50 billion Provider Relief Fund General Distribution*** and must have directly billed their state Medicaid/CHIP programs or Medicaid managed care plans for healthcare-related services between January 1, 2018, and May 31, 2020. HHS is requiring significantly more information from Medicaid providers than from Medicare providers who received money through the General Distribution, including calculating lost revenues due to COVID-19, payer mix information, and any other funding received through the Paycheck Protection Program. The deadline to apply for funding is August 3, 2020.

The enhanced payment portal and detailed information, including terms and condition, is available [here](#). On July 7, 2020, HRSA released a [fact sheet](#) for Medicaid and CHIP providers available on the PRF

website. More general information about eligibility and the application process is also available on [HHS' website](#). CMS has also issued general COVID-19 [FAQs](#) for State Medicaid and CHIP agencies, last updated January 6, 2021.

**Safety Net Hospitals (\$10B).** HHS also announced the distribution of \$10 billion from the PRF to safety net hospitals. This payment is being sent directly to these hospitals via direct deposit the week of the announcement and is going to hospitals that serve a disproportionate number of Medicaid patients or provide large amounts of uncompensated care. Recipients will receive a minimum distribution of \$5 million and a maximum distribution of \$50 million. Qualifying hospitals will have:

- Medicare Disproportionate Payment Percentage (DPP) of 20.2% or greater;
- Average Uncompensated Care per bed of \$25,000 or more per year;
- Profitability of 3% or less, as reported to CMS in its most recently filed Cost Report.

**Additional “Hotspot” Funding for Hospitals.** On June 8, 2020, HHS sent communications to all hospitals asking them to update information on their COVID-19 positive-inpatient admissions for the period January 1, 2020, through June 10, 2020. This information will be used to determine a second round of funding to hospitals in COVID-19 hotspots. ***To be considered for funding from this \$10 billion distribution, hospitals must have submitted their information by June 15, 2020, at 9:00 p.m. ET.***

**Additional \$4 Billion in Relief Payments to Hospitals (7/10/2020).** On July 10, 2020, HHS [announced](#) an additional \$4 billion in aid to hospitals: approximately \$3 billion in funding to hospitals serving a large percentage of vulnerable populations on thin margins and approximately \$1 billion to specialty rural hospitals, urban hospitals with certain rural Medicare designations, and hospitals in small metropolitan areas.

**Children’s Hospitals (8/14/2020).** On August 14, 2020, HHS and HRSA [announced](#) an additional \$1.4 billion in targeted distribution funding to almost 80 free-standing children’s hospitals nationwide.

### [Telehealth](#)

Effective for services starting March 1, 2020 and for the duration of the COVID-19 Public Health Emergency, Medicare will make payment for telehealth services for all Medicare beneficiaries. ASCO has developed a [reference guide](#) for telehealth services and other communication-based technology services including e-visits, virtual visits, and telephone evaluation and management services in Medicare. Additionally, we have created a new [guide](#) regarding telehealth coverage and Medicaid.

In the 2021 Physician Fee Schedule (PFS) Final Rule, released December 2, 2020, CMS permanently added approximately 10 services to the telehealth list beginning in 2021 and temporarily added an additional set of services through December 31, 2021, or the year in which the PHE ends, whichever is later. In the 2022 PFS proposed rule, CMS proposes temporarily extending certain telehealth services beyond the end of the pandemic and finalizing code G2252 for 11-20 minutes of audio-only assessment. See [ASCO in Action](#) for more information on the 2022 PFS changes and refer to this earlier [ASCO in Action](#) for additional details on previous changes.

### **Quality Payment Program (MIPS and APMs): Reporting Flexibilities due to COVID-19**

***Update 5/20/2021: CMS Reweights MIPS 2020 Cost Performance Category to Zero, Opens Applications for the 2021 MIPS Promoting Interoperability Performance Category Hardship Exception and Extreme and Uncontrollable Circumstances Exceptions***

CMS is reweighting the cost performance category in MIPS to 0% from the originally required 15% for the 2020 MIPS performance period (2022 MIPS payment year). The 15% cost performance category weight will be redistributed to other performance categories. This reweighting of the cost performance category applies in addition to the extreme and uncontrollable circumstances (EUC) policies. Clinicians who are not covered by the automatic EUC policy or who did not apply to request reweighting under the EUC policy will still have their cost performance category weighted to 0%.

Applications are now open for the MIPS [Promoting Interoperability Performance Category Hardship Exception](#) and [Extreme and Uncontrollable Circumstances Exception](#) for the 2021 Performance Year. Applications are due to CMS by December 31, 2021.

For additional information, including special circumstances that apply to APM entities participating in MIPS APMs, please see [ASCO in Action](#).

***Update 2/25/2021: CMS Holds Most Physicians Harmless from MIPS Penalties for 2020 Performance Year; Re-opens Application Period for Extreme and Uncontrollable Circumstances Exceptions***

On February 25, 2021, CMS updated its [fact sheet](#) on flexibilities for clinicians participating in MIPS in 2020. For the 2020 performance year, CMS is applying the [MIPS automatic extreme and uncontrollable circumstances \(EUC\) policy](#) to all MIPS eligible clinicians. CMS is also reopening the [MIPS EUC application](#) for individual MIPS eligible clinicians, groups, virtual groups, and Alternative Payment Model (APM) Entities through **March 31, 2021 at 8 p.m. ET. Please note that applications received between now and March 31, 2021, won't override previously submitted data for individuals, groups and virtual groups.**

APM Entities participating in MIPS APMs can submit an [EUC application](#) with some differences from the MIPS EUC policy for individuals, groups, and virtual groups:

- APM Entities are required to request reweighting for all performance categories.
- More than 75% of the MIPS eligible clinicians in the APM Entity must be eligible for reweighting in the Promoting Interoperability performance category.
- Unlike applications for individuals, groups, and virtual groups, an APM Entity's approved application for performance category weighting **will** override previously submitted data.

Please note that if an APM Entity doesn't report for the 2020 performance period (or doesn't have an approved EUC application), their MIPS eligible clinicians will receive a negative payment adjustment in the 2022 payment year.

For additional information, see the 2020 [QPP COVID-19 Response Fact Sheet](#) (last updated May 27, 2021) and [website](#).

For performance year 2020, all ACOs are considered affected by the COVID-19 pandemic PHE, and the Shared Savings Program extreme and uncontrollable circumstances policy applies. For more information on the Shared Savings Program extreme and uncontrollable circumstances policy and its implications beyond the Quality Payment Program, please go to the [Shared Savings Program webpage](#) on CMS.gov. In addition, CMS finalized its proposal to waive the requirement for ACOs to field a Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey for performance year 2020. Consequently, ACOs will receive automatic full credit for the patient experience measures.

In addition to the fact sheet, see the [QPP Exception Applications webpage](#) for more information about eligibility and submission.

## [CMS Flexibilities for Physicians](#)

CMS has issued an array of regulatory revisions and waivers in response to COVID-19 in an effort to reduce patient and provider exposure and increase the capacity of the health care system to see as many patients as possible.

- Relaxed supervision rules to allow for direct supervision to occur through real time audio/visual interaction
- CMS has waived rules stating that Medicare patients in the hospital must be under the care of a physician, which allows PA, NPs to practice to the fullest extent possible.
- CMS will allow Chief Medical Officers (or equivalent in the absence of a CMO) discretion to determine if physician supervision requirements stated in the NCD/LCD are necessary and the discretion to authorize a different physician specialty to provide the service
- CMS will allow physicians to contract with qualified infusion suppliers to perform home infusion under audio/visual supervision of physician when needed

Frequently Asked Questions to Assist Medicare Providers: CMS maintains COVID-19 [Frequently Asked Questions](#) on Medicare Fee-for-Service Billing for Medicare Providers (last updated July 2, 2021). CMS notes that in many instances, the general statements of the FAQs referenced have been superseded by COVID-19-specific legislation, emergency rules, and waivers granted under section 1135 of the Act specifically to address the COVID-19 public health emergency (PHE). The policies set out in this FAQ are effective for the duration of the PHE unless superseded by future legislation.

## [Accelerated and Advance Payment \(AAP\) Program](#)

**On June 24, 2021**, CMS updated its COVID-19 AAP [Repayment and Recovery FAQs](#). (The original FAQs from October, 2020, are still available [here](#).)

On April 1, 2021, CMS released a new [MLN Matters Article](#) announcing that repayment of COVID-19 Accelerated and Advance Payments began on March 30, 2021. The article provides information on how to identify recovered payments and a summary of repayment timeframes.

On October 9, 2020, CMS [announced](#) new repayment terms for Medicare loans made to providers during COVID-19. Loan repayment will now begin one year from the issuance date of each provider or supplier's payment. Providers were previously required to make payments starting in August of 2020.

More detail on these changes is available from this [ASCO post](#) announcing the change and a related CMS [fact sheet](#).

On April 26, 2020 CMS announced that it is reevaluating the amounts that will be paid under its Accelerated Payment Program and suspending its Advance Payment Program to Part B suppliers effective immediately. Beginning on April 26, 2020 CMS will not be accepting any new applications for the Advance Payment Program, and CMS will be reevaluating all pending and new applications for Accelerated Payments.

Funding will continue to be available to hospitals and other health care providers on the front lines of the coronavirus response primarily from the [Provider Relief Fund](#).

The guide ASCO earlier created for members to quickly direct them to the forms and resources needed for the Advanced and Accelerated Payment Programs remains available [here](#).

## [Provider Location](#)

Section 1135 of the Social Security Act will temporarily waive requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state; however, this does NOT override state laws on licensure. For this waiver to apply, the state must also waive these requirements. This waiver applies to Medicare and Medicaid.

### **Workforce Flexibilities**

CMS and the Assistant Secretary of Preparedness and Response (ASPR) maintain a [toolkit](#) to help state and local health care decision makers maximize workforce flexibilities when confronting COVID-19 in their communities. The toolkit includes resources such as information on funding flexibilities, liability protections, and workforce training.

### **Billing, Coding, and Coverage of COVID-19**

ASCO has developed a [quick reference guide](#) on billing and coding for coronavirus testing and diagnosis.

#### [Requests for Early Prescription Refills](#)

MACs will consider on a case-by-case basis whether to pay for greater than a 30-day supply of a Part B drug. Variables included in consideration are the nature of the drug, the patient's diagnosis, the extent and likely duration of disruptions to the drug supply chain during an emergency, and other relevant factors to determine if the advanced refill is reasonable and necessary.

Part D Sponsors may waive prescription refill limits allowing an affected enrollee to obtain the maximum extended day supply available under their plan, if requested and available. They may also relax restrictions on home or mail delivery of prescription drugs.

#### [Prior Authorization](#)

##### *Medicare Advantage:*

Medicare Advantage Organizations may waive prior authorization requirements for tests or services related to COVID-19.

##### *Part D:*

Part D Sponsors may waive prior authorization requirements for Part D drugs used to treat or prevent COVID-19.

#### [Quality, Safety, and Oversight](#)

CMS has released several Quality, Safety, and Oversight memoranda to State Survey Agency Directors with guidance and mechanisms for CMS and state agency inspectors to focus their efforts, personnel and related resources on addressing COVID-19 spread and containment.

- [Suspension of Survey Activities](#): Identifies modifications to the survey and certification processes asking health care providers to focus on infection control and prevention of COVID-19.
- [Hospitals](#): Outlines guidance for hospital administrators regarding screening visitors and patients and monitoring and restricting health care facility staff from working in case of exposure.
- [Outpatient Settings](#): This guidance for outpatient settings (including ambulatory surgical centers, comprehensive outpatient rehabilitation facilities, community mental health centers, rural health centers, federally qualified health Centers) discusses recommendations to mitigate transmission including screening, restricting visitors, cleaning and disinfection, possible closures, and supply scarcity guidance.

- [Nursing Homes](#): Provides guidance to help nursing homes limit the transmission of COVID-19, including guidance for monitoring or restricting staff, managing transfers and admissions of patients with suspected or confirmed COVID-19 infection, and guidance for visitors. Updates require nursing homes to inform residents, their families and representatives of COVID-19 cases in their facilities. On May 13, CMS issued a [toolkit](#) on state actions to mitigate COVID-19 prevalence in nursing homes.
- [Hospice](#): Supports hospices with information about how to address potential and confirmed COVID-19 cases, including the screening, treatment, and transfer of patients to higher level of care, when appropriate.
- [Emergency Departments](#): Provides guidance to hospitals with emergency departments on patient screening, treatment and transfer requirements to prevent the spread of infectious disease and illness, including COVID-19. CMS requires facilities to maintain infection control and prevention policies as a condition for participation in the programs.
- [Home Health and Religious Nonmedical Health Care Institutions](#): Covers how HHAs should screen patients for COVID-19, guidance on monitoring and restricting home health visits for health care staff, and a FAQ section for home health workers.

#### Additional HHS/CMS Resources

- [CARES Act Provider Relief Fund General Distribution FAQs](#)
- [CMS Emergency Website](#)
- [Coronavirus Waivers and Flexibilities](#)
- [Disaster Response Toolkit](#)
- [HRSA FAQ Document](#) (includes Provider Relief Fund, Health Center Testing and Oversight)
- [Medicare Advantage and Part D Flexibilities](#)
- [Medicaid COVID-19 FAQs](#)
- [Medicare Fee For Service Billing FAQs](#)
- [Medicare Provider Enrollment Relief](#)
- [Provider Relief Fund Payment Allocation](#) (High Impact Hospitals and Rural Areas)
- [Requirements for Providers to Make Public Cash Prices for COVID-19 Diagnostic Testing](#)
- [Telehealth for Providers and Patients](#)
- [Telehealth for Providers: What You Need to Know \(Updated March 2021\)](#)

#### Private Payers and Telehealth

Private insurers and other payers have been changing and expanding their coverage policies for telehealth in response to COVID-19. ASCO has developed a [resource guide](#) to help cancer care providers and patients follow this change. This chart will be regularly updated, but we also encourage individuals to independently confirm the coverage details for their respective plans.

#### Drug Enforcement Agency (DEA) Guidance

**Satellite Hospital/Clinic Locations, Receipt and Use of Controlled Substances.** DEA has issued two exceptions to regulations for DEA-registered hospital/clinics: 1. the ability to utilize alternate satellite hospital/clinic locations under their current DEA registrations without the need to apply for a separate DEA registration for the alternate site; and 2. distributors can ship controlled substances directly to these alternate satellite hospital/clinic locations that do not have their own DEA registrations (i.e. non-

registered). These two exceptions are in effect from April 10, 2020, until the public health emergency declared by the Secretary of Health and Human Services (HHS) ends or the DEA specifies an earlier date.

**Exception to the “Five Percent” Rule.** Under existing DEA regulations, a practitioner who is registered to dispense may distribute limited amounts of controlled substances to another practitioner for the purpose of general dispensing by the other practitioner to patients, if certain conditions are met. Among these conditions is that the amount a practitioner so distributes to other practitioners during a calendar year cannot exceed five percent of the total number of dosage units of all controlled substances that the practitioner dispenses and distributes during that year. The DEA has also provided an exception to this “five percent” rule, allowing for the distribution of controlled substances of more than the five percent that a practitioner can distribute to another practitioner during the calendar year. This exception is in effect from January 1, 2020, until the public health emergency ends or the DEA specifies an earlier date or otherwise first modifies or withdraws this exception. the date this exception ends.

The full guidance for these exceptions is available [here](#).

## FDA Actions on Drug Shortages: Temporary Compounding Policies; Updated Drug Lists; “In-use” Times

**General Policies.** The FDA has issued a [temporary policy](#) (last updated 5/21/2020) covering the compounding of certain drugs for hospitalized patients by outsourcing facilities during the COVID-19 public health emergency. The FDA has also issued a [temporary policy](#) (last updated 5/21/2020) covering the compounding of certain drugs by pharmacy compounders not registered as outsourcing facilities. This policy allows for the compounding of a drug that is essentially a copy of a commercially available drug, or for providing a drug to a hospital without obtaining a patient-specific prescription, if specific circumstances are present and certain conditions are met. This policy will end with the termination of the public health emergency or at an earlier date specified by FDA.

**Specific Drugs.** The FDA has issued a [temporary policy](#) on the repackaging and combination of propofol drug products; propofol is on the FDA drug shortage list and is a critical drug for the treatment of patients extremely ill with COVID-19. On July 13, 2020, FDA added dexamethasone sodium phosphate to the lists of drugs for temporary compounding for hospitalized patients by [outsourcing facilities](#) and [pharmacy compounders](#) not registered as outsourcing facilities.

**“In-use Times” (August 4, 2020).** FDA is aware that some health care facilities and providers are facing challenges in maintaining adequate supplies of certain drugs needed to treat patients with COVID-19. The “in-use time” is the maximum amount of time that can be allowed to elapse between penetration of a container-closure system containing a sterile drug product, or after a lyophilized drug product has been reconstituted, and before patient administration.

FDA has provided a list of drugs, most used in ventilated patients, to which the following applies:

If there is a need to use these products beyond the labeled in-use time to help ensure access to the drug for patients, it is important that this period be as short as possible, and for a maximum of:

Four (4) hours for a refrigerated storage condition (if any), or

Two (2) hours for any labeled room temperature in-use time (if any)

This extended use applies to either the refrigerated or the room temperature in-use storage condition and not both storage conditions even if both refrigerated and room temperature in-use lifetimes are provided in the labeling.

See the FDA's [webpage](#) for important safety information and additional details.

**FDA Device Shortage List.** On August 14, 2020, the FDA announced the availability of its [device shortage list](#). The device shortage list reflects the categories of devices that the FDA has determined to be in shortage at this time and will be updated as the COVID-19 pandemic evolves. In addition, the FDA is providing a list of medical devices for which manufacturing has been permanently discontinued.

Categories of devices in the device shortage list are:

- Personal Protective Equipment
- Testing Supplies and Equipment
- Ventilation-Related Products

Unlike the drug shortage list maintained by the FDA, no manufacturers are identified in the device shortage list. The FDA has determined that “disclosure of the manufacturer’s name of the devices determined to be in shortage during the COVID-19 PHE will adversely affect the public health by increasing the potential for hoarding or other disruptions in device availability to patients.”

For further information on previous and current FDA initiatives related to COVID-19, please see this “[At-a-Glance-Summary](#)” released by the FDA on March 26, 2021, which highlights the FDA’s programs and activities during the pandemic.

#### NIH Resources

- [Information for Global Health Researchers](#) (Fogarty International Center)
- [Management of patients on trials](#) (NCI)
- [NCI Main COVID-19 Information Page](#)
- [NCI CIRB Information about COVID-19](#)
- [NIH Resources on Coronavirus](#)
- [NIH Grant Applicant/Recipient Guidance](#)

#### CDC Resources

- [COVID-19 Situation Summary](#)
- [Framework for Health Care Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic](#)
- [FAQ](#)

#### FDA Resources

- [COVID-19 Updates Main Page](#)
- [COVID-19 Drug Development Main Page](#)
- [COVID-19 Emergency Use Authorizations](#)
- [Drug Shortage Information](#)

- [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)
- [Surgical Mask and Gown Conservation Measures](#)

#### Additional Federal Agency Information

- [Occupational Safety and Health Administration \(OSHA\) COVID-19 Resources](#)
- [AHRQ COVID-19 Resources](#)

#### Other Resources

- [AMA COVID-19 Resource Center for Physicians](#)
- [Association of State and Territorial Health Officials \(ASTHO\) Fact Sheet on State Emergency Declarations and Authorities](#)