

End Stage Renal Disease (ESRD) Facilities: 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 has 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 aims to evaluate CMS-issued PHE blanket waivers and flexibilities to prepare the health care system for operation after the PHE. This review is being done in three concurrent phases:

1. CMS is assessing the need for continuing certain blanket 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 is assessing 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 identifies barriers and opportunities for improvement, the needs of each person and community served will be 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.

COVID-19 Vaccines

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 COVID-19 public health emergency (PHE).

Payment After the End of the PHE

CMS will continue to pay approximately \$40 per dose for administering COVID-19 vaccines in outpatient settings for Medicare beneficiaries through the end of the calendar year that the PHE ends.

Effective January 1 of the year following the year that the COVID-19 PHE ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines.

Additional Payment for Administering the Vaccine in the Patient's Home

CMS also established an additional payment amount of approximately \$35.50 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, and we geographically adjust the additional amount and administration rate based on where the provider or supplier administers the vaccine.

Additional Payment for Administering the Vaccine in the Patient's Home After the End of the PHE

We'll continue to pay a total payment of approximately \$75 per dose to administer COVID-19 vaccines in the home for certain Medicare patients through the end of the calendar year that the COVID-19 PHE ends.

Note: The [Calendar Year 2023 Physician Fee Schedule](#) proposed rule includes proposals that could impact these policies, and we anticipate issuing the final rule later this year.

More information: COVID-19 vaccine toolkits

- [Providers](#)
 - [Payment](#)
 - [Billing](#)
 - [Coding](#)
- [Health & Drug Plans](#)
- [State Medicaid programs](#)

COVID-19 Monoclonal Antibodies

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 COVID-19 public health emergency (PHE), 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.

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.

More information: [COVID-19 Monoclonal Antibodies](#)

Payment After the End of the PHE

Effective January 1 of the year following the year that the COVID-19 PHE ends, CMS will pay for monoclonal antibodies:

- 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 would not be considered renal dialysis services, and would not be paid under the ESRD PPS. Monoclonal antibodies furnished to ESRD patients may be separately payable to the dialysis facility if the drug was not used for the treatment of ESRD. The facility must include the modifier AY to indicate it was not for the treatment of ESRD.

Note: The [Calendar Year 2023 Physician Fee Schedule](#) proposed rule includes proposals that could impact these policies, and we anticipate issuing the final rule later this year.

Reducing Administrative Burden

- *Training Program and Periodic Audits:* CMS has been waiving the requirement at §494.40(d) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities. CMS will end this waiver at the conclusion of the COVID-19 PHE.

- *Equipment Maintenance & Fire Safety Inspections:* CMS has been waiving requirements at §494.60(b) and §494.60(d) to reduce non-essential people entering the facility to reduce risk of exposure to the virus. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency. **(This waiver terminated on 6/6/2022).**
- *Emergency Preparedness:* CMS has been waiving the requirements at §494.62(d)(1)(iv), which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program that, at a minimum, its patient care staff maintains current CPR certification. CMS has been waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes. CMS will end this waiver at the conclusion of the COVID-19 PHE.
- *Ability to Delay Some Patient Assessments:* To ensure that dialysis facility staff can focus on the increased care demands related to the COVID-19 pandemic, CMS has been waiving certain requirements at §494.80(b) related to the frequency of assessment for patients admitted to the dialysis facility. CMS has been waiving the “on-time” requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. CMS is not waiving subsections (a) or (c) of 42 CFR §494.80. We maintain expectations for conducting the assessment, ensuring the adequacy of the dialysis treatment, and assessing the patient’s needs when there is a change in condition.

Specifically, CMS has been waiving:

- §494.80(b) (1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30-calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**
- §494.80(b) (2): A follow up comprehensive reassessment must occur within three months after the completion of the initial assessment to provide information to adjust the patient’s plan of care specified in §494.90. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**
- *Home dialysis machine designation — clarification:* The ESRD Conditions for Coverage (CfCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer’s directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and

disinfected to minimize the risk of infection based on the requirements at 42 CFR 494.30 *Condition: Infection Control* if used to treat multiple patients. This waiver will end at the conclusion of the COVID-19 PHE.

- *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 C.F.R. §§ 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 C.F.R. § 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 C.F.R. § 424.514, resumed collecting application fees.)***
 - *Revalidation*: CMS postponed all revalidation actions. This did not prevent a provider who wants 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 reporting 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 Contractor (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 COVID-19 PHE ends, these flexibilities will continue to apply, consistent with existing regulatory authority.

Medicare Telehealth for ESRD

- *Time period for initiation of care planning and monthly physician visits:* CMS is modifying two requirements related to care planning, specifically:
 - §494.90(b)(2): CMS has modified the requirement that the dialysis facility implement the initial plan of care within the latter of 30-calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the

- requirement for monthly or annual updates to the plan of care within 15 days of the completion of the additional patient assessments. CMS has been waiving the time requirement for plan of care implementation during the time period of the national emergency.
- §494.90(b)(4): CMS has modified the requirement that the ESRD dialysis facility ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS has been waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities; e.g., phone calls, to ensure patient safety.

CMS will end this waiver at the conclusion of the COVID-19 PHE.

- *Dialysis home visits to assess adaptation and home dialysis machine designation:* CMS has been waiving the requirement at 494.100(c)(1)(i), which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home or long-term care facility, reference QSO-20-19-ESRD. CMS will end this waiver at the conclusion of the COVID-19 PHE.

Temporary Expansion Sites

- *Special Purpose Renal Dialysis Facilities (SPRDF) designation expanded:* During the PHE, CMS has authorized the establishment of SPRDFs to address access to care issues due to COVID-19 and the need to mitigate transmission among this vulnerable population. This did not include the normal determination regarding whether there was a lack of access to care as that standard was automatically met during the nationwide PHE. Approval as Special Purpose Renal Dialysis Facility does not require federal survey prior to providing services. CMS will end this flexibility at the conclusion of the COVID-19 PHE.
- *Furnishing dialysis services on the main premises:* ESRD requirements at §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS has been waiving this requirement to allow dialysis facilities to provide service to its patients in nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents are under the direction of the same governing body and professional staff as the resident's usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective, and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: furnish all dialysis care and

services; provide all equipment and supplies necessary; maintain equipment and supplies in the off-premises location; and complete all equipment maintenance, cleaning, and disinfection using appropriate infection control procedures and manufacturer's instructions for use. **CMS will end this waiver at the conclusion of the COVID-19 PHE.**

- *Clarification for billing procedures:* Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center bills Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center also applies condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider has their trained personnel administer the treatment in the SNF/NF. In addition, the provider follows the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA-approved labeling must be adhered to (§ 494.100) and it must be maintained and operated in accordance with the manufacturer's recommendations (§ 494.60) and follow infection control requirements at (§ 494.30).

Workforce

- *Dialysis Patient Care Technician certification:* CMS has modified the requirement at § 494.140(e)(4) for patient care dialysis technicians, which requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis patient care technician for newly employed dialysis patient care technicians. We are aware of the challenges that technicians are facing with the limited availability and closures of testing sites during the time of this crisis. CMS has allowed patient care technicians to continue working even if they have not achieved certification within 18 months or have not met on-time renewals. CMS will end this flexibility at the conclusion of the COVID-19 PHE.
- *Transferability of physician credentialing:* CMS has modified the requirement at §494.180(c)(1), which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. CMS has allowed physicians who are appropriately credentialed at a certified dialysis facility to provide care at designated isolation locations (or separate COVID-19 only facilities designed to mitigate transmission of the virus) without separate credentialing at that facility. This has been implemented while remaining consistent with a state's emergency preparedness or pandemic plan. CMS will end this flexibility at the conclusion of the COVID-19 PHE.

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>.
- CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- CMS has released guidance to describe standards of practice for infection control and prevention of COVID-19 in dialysis facilities. We also described additional flexibilities for dialysis facilities to mitigate transmission and expand home dialysis options. <https://www.cms.gov/files/document/qso-20-19-esrd.pdf>.